

PROGRAM CURRICULUM
of
School of Pharmaceutical Sciences
(B.Sc. Clinical)

(Program Code:)

[Applicable w.e.f. Academic Year 2025-26]



JIGYASA UNIVERSITY

Formerly

Hingiri Zee University, Dehradun

(Estd. Under Uttaranchal State Act.No.17, 2003.Approved by UGC Under Sec.2(f))

Post Office Selaqui, Chakrata Road, Dehradun, Uttarakhand,248011

Vision of University

We provide the environment to ignite, nurture, and unleash your potential and talent

Mission Statement

1. Progressive educational proficiencies that stimulate holistic development.
2. Enhancing experiential learning through endorsing an inclusive mindset.
3. Advancing research, nurturing innovations, and catalyzing entrepreneurship.
4. Cultivation of leadership qualities with a strong sense of values and ethics.

Vision of School of Pharmaceutical Sciences (SPS)

To become a global leader in pharmacy education, clinical research, and service, committed towards providing a transformative learning experience in a collaborative and diverse environment focused on improving the health and well-being of the communities.

Mission Statements of SPS

- **M1.** To improve the well-being and quality of life of individuals and communities by educating students.
- **M2.** To prepare students to become pharmacists and pharmaceutical scientists who will be leaders in the pharmacy profession.
- **M3.** Research in the pharmaceutical & clinical sciences and its translation into health care

About the Program

A. Introduction:

Bachelor of Clinical Research (B.Sc. CR) is a three-year undergraduate course that teaches persons the knowledge and skills required to perform and manage clinical research investigations. Clinical Research courses are often provided at several levels of education to undergraduate and are designed for a diverse variety of professionals, including healthcare providers, scientists, researchers, and anyone interested in pursuing a career in Clinical Research.

The health sector is a significant part of the economy. It not only provides health care services but also gives excellent academic and career opportunities for students. Clinical research is one of the most prominent fields of study these days. It is the study of healthcare science that focuses on human research to improve treatments and pharmaceuticals, develop new diagnostic procedures, and increase information about various diseases and disorders.

B. Credit Framework of 3 Year Bachelor's Degree in Clinical Research

Semesters (2 Semesters = 1Year)	Core Courses		Discipline Specific Elective Courses		Multidisciplinary Courses	Ability Enhancement Courses	Skill Enhancement Courses	Value Added Courses	Capstone Project & Research Project	Total Credits	No. of Courses/Year
	Major Core Courses (MCC) (4c)	Major Discipline Course (MDC) (4c)	DS E (Major) (3c)	DS E (Minor) (3c)	MLC (3c)	AEC (3c)	SEC (3c)	VAC (2c)	CAP (4c) & REP (12c)		Total Credits/Year
I	No. of Courses	03					04			07	22
	Course Credits	12					10			22	
II	No. of Courses	03				01	03			07	22
	Course Credits	12				04	06			22	
II I	No. of Courses	03		01	01	01	01			07	24
	Course Credits	12		03	03	04	02			24	
I V	No. of Courses	03			02	01	01			07	24
	Course Credits	12			06	04	02			24	
V	No. of Courses	03			02		01		01	07	24
	Course Credits	12			06		04		02	24	
V I	No. of Courses								01	01	20
	Course Credits								20	20	
No. of Courses										36	36
Course Credits										136	136

C. National Higher Education Qualifications Framework (NHEQF) levels:

NHEQF Level	NHEQF Level	NHEQF Level	NHEQF Level	NHEQF Level
Level 5	Undergraduate Certificate	Completion of 1st year of UG program	~40 credits	Foundational knowledge and skills; eligible for vertical mobility
Level 6	Undergraduate Diploma	Completion of 2 years of UG program	~80 credits	Broader subject understanding; vocational and academic skills
Level 7	Bachelor's Degree (3 years)	10+2 (Senior Secondary)	~120 credits	Core disciplinary knowledge and cognitive skills
Level 7.5	Bachelor's Degree with Honours (4 years)	Based on strong academic performance	~160 credits	Advanced disciplinary depth; research exposure (Capstone)
Level 8	Bachelor's Degree with Research (4 years)	75%+ in previous semesters; research orientation	~160 credits + Research Project	Research, innovation, and preparedness for PG or direct PhD

D. Academic Bank of Credits (ABC):

In alignment with the National Education Policy (NEP) 2020, the Academic Bank of Credits (ABC) facilitates a flexible curriculum framework and promotes interdisciplinary/multidisciplinary academic mobility among students across various Higher Educational Institutions (HEIs) through an appropriate credit transfer system. Accordingly, the School of Business Studies, under Jigyasa University, Dehradun, has developed a comprehensive four-year undergraduate program.

As a prerequisite, students/learners are required to register on the Academic Bank of Credits (ABC) portal. The credits earned during the study will be digitally stored in the ABC account. Learners must complete their program as per the guidelines of the UGC's ABC policy. Please note that the validity of earned credits is limited to seven years (or as per the latest advisory from the competent authority). Additionally, each credit earned may only be used once and cannot be reused for multiple programs or purposes.

E. Curriculum Framework:

The B.Sc. Clinical curriculum framework is designed in accordance with the guidelines of the University and emphasizes a comprehensive approach to undergraduate clinical education. The courses are broadly classified as follows: : Major Core Courses (MCC), Major Discipline Courses (MDC), Discipline Specific Elective Courses- Major& Minor(DSE), Multidisciplinary Courses (MDC), Skill

Enhancement Courses (SEC), Ability Enhancement Courses (AEC), Value-Added Courses (VAC), Capstone Projects (CAP), and Research Projects (REP)

This structured framework ensures that students acquire in-depth theoretical knowledge, practical skills, and research competencies essential for professional clinical practice, healthcare industry readiness, and evidence-based pharmaceutical care. It also promotes critical thinking, multidisciplinary exposure, and lifelong learning, preparing graduates to meet the evolving challenges of the healthcare and clinical research sectors.

I. Major Core Courses (MCC):

Major Courses (MCC) encompass a comprehensive range of subjects designed to provide students with a strong foundation in clinical research, biomedical sciences, and healthcare management. These courses are structured to enhance analytical reasoning, scientific aptitude, ethical understanding, and research-oriented problem-solving skills.

The curriculum integrates key domains such as clinical research methodology, pharmacology, medical therapeutics, bioethics, biostatistics, pharmacovigilance, and regulatory affairs, ensuring that graduates are equipped with both theoretical knowledge and practical competencies relevant to the clinical and healthcare industries.

The MCC includes core courses such as Fundamentals of Clinical Research, Pharmacology, Medical Therapeutics, Fundamentals of Pharmacovigilance, Global Regulations of Clinical Trials, and Clinical Data Management, which collectively develop students' understanding of drug development, clinical trial design, patient safety, and regulatory compliance. Advanced courses such as Molecular Diagnostics, Hospital Management and Law, and Research Projects (Minor and Major/Internship) prepare students for diverse career paths in clinical operations, data analysis, and health research.

II. Major Discipline Courses (MDC)

Major Discipline Courses (MDC) provide students with a strong foundation in clinical research, biomedical sciences, and healthcare management, integrating theoretical understanding with applied professional skills. These courses are designed

to enhance analytical thinking, problem-solving abilities, ethical awareness, and research competence essential for careers in the clinical and healthcare sectors.

The curriculum encompasses key domains such as Clinical Research Methodology, Pharmacology, Medical Therapeutics, Pharmacovigilance, Biostatistics, Bioethics, and Regulatory Affairs, providing students with in-depth knowledge of clinical trial operations, drug development, and patient safety.

Advanced courses including Clinical Data Management, Molecular Diagnostics, Hospital Management and Law, Research Methodology, and Project Work (Minor and Major/Internship) prepare learners for professional roles in clinical operations, data analysis, regulatory compliance, and applied health research.

III. Discipline Specific Elective Courses - Major & Minor (DSE)

Aligned with NEP 2020, the B.Sc. Clinical program offers specializations that provide theoretical knowledge, practical exposure, and hands-on training, enabling students to develop domain-specific competencies. Integrated into later semesters, these modules ensure a strong foundation in core clinical sciences before advancing to specialized clinical study, preparing students for both industry and research roles.

IV. Multidisciplinary Courses (MLC)

Multidisciplinary Courses (MLC) in the B.Sc. Clinical program are designed to integrate knowledge from various scientific and healthcare disciplines, providing students with a comprehensive understanding of clinical practice and healthcare systems. These courses extend beyond core clinical subjects to show how interdisciplinary knowledge supports problem-solving, innovation, and informed decision-making in patient care. They also emphasize adaptability, critical thinking, and ethical responsibility as essential qualities for competent healthcare professionals.

V. Skill Enhancement Courses (SEC)

Skill Enhancement Courses (SECs) in the B.Sc. Clinical program are designed to equip students with practical, professional, and industry-relevant competencies beyond the core clinical curriculum. These courses develop technical and analytical skills, emphasizing real-world applications and hands-on, job-oriented abilities essential for modern healthcare practice.

The curriculum includes five key courses:

1. Clinical Laboratory Skills – introduces essential laboratory and clinical techniques, including diagnostic procedures and patient assessment.

2. Analytical Methods in Clinical Practice – focuses on modern methods for analyzing clinical samples, data interpretation, and validation of results.
3. Patient Care Skills – equips students with practical knowledge for patient management, therapeutic monitoring, and clinical decision-making.
4. Quality Assurance and Regulatory Compliance – provides hands-on experience in maintaining healthcare standards and adhering to regulatory guidelines.
5. Digital Tools in Clinical Practice – prepares students to use digital technologies and software applications relevant to modern clinical settings.

VI. Ability Enhancement Courses (AEC)

While generic professional skills such as communication, ethics, and regulatory awareness are implicitly covered, this category formalizes them by introducing dedicated courses in professional communication, ethical clinical practice, data analysis, and scientific reasoning. These courses strengthen students' professional competence and prepare them for responsible and effective roles in clinical and healthcare settings.

VII. Value-Added Courses (VAC)

This category is not part of the university marksheet, but is offered as a supplementary certificate. Students receive a certificate upon successful completion of the module, which highlights their skill development and readiness for industry, research, and professional practice. It is retained for supplementary modules such as Entrepreneurship, Intellectual Property in Clinical Science, and Digital Tools etc. in Clinical Sciences.

VIII. Capstone Project (CAP):

The Capstone Project (CAP) in the B.Sc. Clinical program provides students with an opportunity to integrate and apply the knowledge and skills acquired throughout the course to real-world clinical and healthcare challenges. It serves as the culmination of learning, emphasizing critical thinking, problem-solving, research aptitude, and professional competence.

Students undertake projects in areas such as clinical data analysis, hospital-based studies, patient care evaluation, biomedical research, epidemiology, or public health assessment. Under faculty supervision, they plan, execute, and present a

comprehensive project demonstrating their ability to collect data, interpret results, and propose practical, evidence-based solutions.

The Capstone Project encourages independent learning, innovation, and interdisciplinary application, bridging theoretical knowledge with practical implementation. Successful completion enhances students' research and professional skills, preparing them for advanced studies, healthcare industry roles, and research-oriented careers.

IX. Research Project (REP):

Although general project work is a standard component of undergraduate programmes, the term “research project” is retained separately in the B.Sc. Clinical Research curriculum to emphasise students' engagement in research-oriented activities. This category highlights deeper involvement in laboratory, clinical, or community-based research that goes beyond routine project assignments. It allows students to develop stronger competencies in scientific inquiry, research design, data interpretation, ethical practices, and evidence-based problem-solving, thereby strengthening their preparedness for professional roles and higher studies in clinical and biomedical research.

Program Matrix

Matrix Course Category Name	Course Category Code	Number of Courses	Credits	Total Course Credits
Major Core Course	MCC	15	4	60
Skill Enhancement Courses	SEC	2	4	8
Skill Enhancement Courses	SEC	2	3	6
Skill Enhancement Courses	SEC	4	2	8
Skill Enhancement Courses	SEC	2	1	2
Discipline Specific Elective Courses	DSE	1	3	3
Multidisciplinary Courses	MLC	5	3	15
Ability Enhancement Courses	AEC	3	4	12
Capstone Project	CAP	1	2	2
Capstone Project	CAP	1	20	20
TOTAL		36		136

Types of Courses (Non-Credits)

Category Name	Number of Courses	Total Number of Course
SEC	Soft Skill Enhancement	01
AEC	Social Engineering/Yoga/Sports/Extra Curricular activity/MOOCs	08
AEC	Webinar	02

Whereas : NC – Non Credit, SEC – Skill enhancement Course, AEC – Ability Enhancement Course, MLC – Multidisciplinary Course

F. Graduate Attributes (GA):

The Graduate Attributes (GAs) underpinning the B.sc. in Clinical Research program have been adopted in alignment with the National Education Policy (NEP) 2020, University Grants Commission (UGC) guidelines, and the National Higher Education Qualifications Framework (NHEQF). These attributes serve as the foundational principles for defining the Program Educational Objectives (PEOs) and Program Outcomes (POs) outlined below. The curriculum is thus designed to ensure students develop the competencies, values, and capabilities envisioned for undergraduate business education in India.

G. Program Educational Objectives (PEOs)- (B.sc. CR)

1. **PEO1:** To equip students with the fundamentals of clinical research.
2. **PEO2:** To understand and analyze the impact of clinical research in a global, economic, environmental and social context.
3. **PEO3:** Analyze advanced critical thinking skills necessary to enhance employment opportunities for advancement within the clinical research industry.
4. **PEO4:** Apply the evolving regulations, standards, and practices of ICH GCP in various therapeutic conduct trials.
5. **PEO5:** Analyzing effectively communicate and collaborate with health care providers and regulatory agencies to develop culturally diverse domestic and global strategies for biopharmaceutical product approvals.

H. Program Outcomes (POs) - (B. sc. CR)

PO	Outcome
PO1	Understand the Clinical research and basic medical knowledge: Apply knowledge of basic medical sciences and clinical research to be a successful member of the research team or a individual.
PO2	Apply the Modern tool usage: Create, select and apply appropriate techniques, resources and modern tools in clinical data management with an understanding of the limitations.
PO3	Comprehensive understanding of the processes, protocols, and regulations involved in conducting clinical trials and investigations.
PO4	Identify the basis, concepts, and determinants; apply prevalence of diseases in human populations.
PO5	Analyze professional and ethical responsibilities in clinical research practice by following standards, norms and practices of ethical and regulatory bodies.
PO6	Describe and demonstrate management/ Analyze the leadership skills and theories that can lead or manage effectively in a healthcare environment.
PO7	Understand the most important ethical issues in clinical research and analyze prepare necessary documents for Institutional Review Board process
PO8	Understand about the principles of medical research, data collection and analysis , ethical considerations, and patient safety.
PO9	Demonstrate and Evaluating skills in writing and communicating results of research scientific presentations and publications.

I. Mapping of PEOs & POs in B.sc. CR Matrix

PEO – PO Attainment Matrix

PO→ PEO ↓	PO1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9
1	3	2	3	1	2		2	3	2
2	2	2	3	2	3	2	2	2	1
3	2	3	2	1	2	3	1		2
4	2	1	3		3		3	2	2
5	2	2	2	1	3	2	2	1	3

Note: In alignment with Outcome-Based Education (OBE) principles, the mapping of Program Educational Objectives (PEOs) to Program Outcomes (POs) is presented using a **quantitative scale (1–3)**, where:

- 1 indicates a low level of contribution
- 2 indicates a moderate level of contribution
- 3 indicates a high level of contribution

This mapping ensures that each PEO is **progressively achieved through the attainment of relevant POs**, thereby providing a structured and measurable approach to evaluating the effectiveness of the program in delivering its long-term educational goals.

J. Pedagogy, Andragogy, and Unique practices adopted:

Pedagogy refers to the art and science of teaching, particularly within academic and professional disciplines. In the B.Sc. Clinical Research programme, the institute follows a comprehensive and learner-centered teaching approach designed to build strong theoretical foundations, practical competence, and research capability.

Alongside structured classroom lectures, students engage in a wide range of experiential and interactive learning methods, including:

- Laboratory practicals and simulations – to develop hands-on skills in clinical laboratory techniques, biomedical testing, sample handling, and data recording.
- Case studies, protocol analysis, and problem-solving exercises – to strengthen clinical reasoning, understanding of study designs, ethical decision-making, and application of regulatory guidelines.
- Clinical site visits, hospital exposure, and interactions with research units – to familiarize students with real-world clinical workflows, trial documentation, patient management processes, and Good Clinical Practice (GCP) environments.
- Group discussions, journal clubs, and seminar presentations – to enhance scientific communication, teamwork, critical appraisal of literature, and evidence-based thinking.
- Project-based learning, including Capstone Projects and Research Projects, to integrate multidisciplinary knowledge, develop research aptitude, and encourage independent investigation in clinical, biomedical, or community-based contexts.

These pedagogical strategies ensure that students gain holistic knowledge of clinical research operations, regulatory frameworks, ethics, trial management, and scientific methodology. By combining lectures, practical sessions, interactive learning, and research engagement, the B.Sc. Clinical Research pedagogy prepares learners for professional roles in clinical trials, pharmacovigilance, medical writing, regulatory affairs, and biomedical research, while also equipping them for advanced studies in the health sciences.

1. Orientation and Bridge Program:

At the commencement of the B.Sc. Clinical Research programme, the School will organize a comprehensive Orientation Program to welcome and guide newly enrolled students. The program aims to familiarize students with academic expectations, institutional values, professional responsibilities, and available support systems, thereby laying a strong foundation for their journey in clinical research and health sciences education.

The Orientation Program plays a crucial role in easing students into university and professional life. It introduces students to the campus environment, faculty members, academic policies, laboratories, research facilities, and clinical or hospital-linked units. Spanning approximately one week, the program fosters interaction among peers, faculty, and support staff, creating a sense of belonging and community. It also ensures that students understand institutional rules, academic expectations, and available learning resources, enabling a smooth and confident transition into the B.Sc. Clinical Research programme.

Aligned with the objectives of modern higher education and the competencies required in clinical research, the Orientation Program is structured to provide holistic development, academic readiness, and professional growth. The key components include:

- **Introduction to College and Professional Life:** Supporting students in adapting to academic, laboratory, and clinical environments related to research and healthcare.
- **Integration with University Culture:** Helping students understand the social, ethical, and academic values that guide institutional practices.
- **Faculty and Peer Interaction:** Encouraging meaningful connections between students, faculty, mentors, and programme coordinators to strengthen engagement and support.
- **Linkages with Society and Healthcare Environment:** Highlighting the role of clinical research in public health, patient safety, community wellbeing, and ethical medical practices.
- **Philosophy of Clinical Research Education & Pedagogy:** Introducing students to the goals, values, and evidence-based teaching methodologies integral to clinical and biomedical education.

- **Academic Foundation and Bridge Courses:** Addressing gaps in core subjects such as biology, chemistry, mathematics, medical terminology, and computer literacy to ensure academic preparedness.
- **Personality Development and Professional Skills:** Developing communication, leadership, teamwork, ethics, and interpersonal skills essential for clinical and research environments.
- **Information Technology and Digital Skills:** Enhancing digital literacy in areas such as data entry, electronic health records, clinical documentation, research databases, and basic biostatistical tools.

This Orientation Program ensures that students begin the B.Sc. Clinical Research programme with confidence, clarity, and readiness to meet the academic, research, and professional expectations of their chosen field.

2. Experiential and Holistic Learning Approach:

To foster experiential learning beyond conventional classroom instruction, the B.Sc. Clinical Research programme integrates a variety of participatory and applied pedagogical approaches. These methodologies are designed to reinforce theoretical knowledge with practical application, enhance critical thinking, and develop professional competencies essential for clinical research and healthcare environments.

Students are encouraged to actively participate in School Clubs and Professional Development Forums, including:

- **VIBGYOR Club** – promoting creativity, interdisciplinary learning, and holistic personal development.
- **Young Leaders' Club** – enhancing leadership, teamwork, communication, and organizational skills.

The programme employs a wide range of interactive and applied teaching–learning methods, including:

- **Case-based Discussions:** Applying theoretical concepts to real-world clinical, biomedical, and research scenarios.

- **Role-plays, Group Assignments, and Presentations:** Developing teamwork, communication, and problem-solving skills essential for professional research and healthcare practice.
- **Video-assisted Learning Sessions:** Facilitating visual understanding of complex laboratory techniques, clinical procedures, and study protocols.
- **Field Assignments, Live Research Projects, and Hospital/Industry Visits:** Providing hands-on exposure to clinical trials, research laboratories, hospitals, and community health settings.
- **Expert-led Interactive Sessions:** Enabling knowledge transfer from experienced researchers, clinicians, and healthcare professionals.
- **Co-curricular and Student Development Initiatives:** Encouraging holistic growth through participation in seminars, workshops, competitions, and community outreach programs.
- **Mentorship Programs:** Offering guidance on academic planning, career development, and professional skills.
- **Workshops and Seminars:** Strengthening practical competencies, research aptitude, and awareness of current trends in clinical research and biomedical sciences.

These experiential and participatory pedagogies ensure that B.Sc. Clinical Research students gain not only strong conceptual knowledge but also the practical skills, ethical understanding, and professional competencies required to excel in clinical research, healthcare, and biomedical research domains. By integrating interactive learning, real-world exposure, and mentorship, the programme prepares students to meet the demands of modern research and healthcare professions.

3. Library and E – Learning Access:

Course faculty actively encourage B.Sc. Clinical Research students to make regular and purposeful use of the University Library, guiding them to effectively utilize its extensive collection of books, journals, reference materials, and digital resources. These resources support academic learning, subject-specific research, laboratory work, and the overall development of knowledge in clinical research, biomedical sciences, and healthcare practices.

In addition, students have access to a wide range of e-learning resources through individual logins on the University’s ERP and digital learning platforms. This facilitates continuous learning beyond

classroom instruction, enabling students to engage in self-directed study, online research, simulation exercises, data analysis, and virtual laboratory or clinical trial learning experiences.

K. Question Paper and Assessment Tools

General Note on Assessment and Evaluation

Our university follows a *Continuous Evaluation System* that ensures students are assessed consistently and fairly throughout the semester. This system includes three main components: *Internal Assessments*, *Mid-Term Examinations*, and *End-Term Examinations*.

- As part of Internal Assessments, faculty members may adopt a variety of tools such as Surprise Quizzes, Assignments (Group or individual assignments, case study presentations and discussions, role plays, group discussions), and other interactive evaluation methods. These are designed to assess not just subject knowledge but also communication, collaboration, and critical thinking skills. The specific tools and weightage for each course will be clearly mentioned in the Course Syllabus and Assessment Scheme, which is shared at the beginning of the semester.
- All assessments across programs are conducted as per the guidelines outlined in the Examination Manual (EM) issued by the Controller of Examinations (CoE). This ensures consistency, fairness, and academic integrity in both theory and practical examinations.
- Course faculty are responsible for preparing question papers for internal, mid-term, and end-term exams in line with the EM. Questions are developed using the Bloom's Taxonomy (BT) framework, which covers a range of learning levels—from basic understanding to advanced application and analysis.
- Each question is aligned with specific Course Outcomes (COs) to ensure that assessments are outcome-based. During evaluation, faculty will mark responses CO-wise, and this will be reflected in the answer sheet's marks column. This approach helps both faculty and students understand which learning outcomes have been achieved and where further improvement is needed.

This structured and student-centric assessment system encourages continuous learning and academic growth, while supporting the goals of Outcome-Based Education (OBE).

L. Program Structure

Program Matrix B.sc Clinical Research (B.sc. CR)

S. No.	Course Code	Course Name	Category	Numbers of Hours/Week			C
			Core / Elective / Others	L	T	P	
SEMESTER I							
1	BCR 111	Management Concepts	MCC	3	1	-	4
2	BCR 112	Spoken English	SEC	3	1	-	4
3	BCR 113	Introduction to Healthcare-I	MCC	3	1	-	4
4	BCR 114	Fundamentals of Clinical Research	MCC	3	1	-	4
5	BCR 115	Mind Management and Human Values	SEC	2	1	-	3
6	BCR 116	Environmental Science -I	SEC	2	-	-	2
7	SSE 001	Soft Skill Enhancement-I	SEC	1	-	-	1
8	MO 001	MOOCs/Foreign Language	AEC				NC
9	SE 001	Social Engineering/Yoga/Sports/Extra Curricular activity	AEC				NC
Total				17	5		22
SEMESTER II							
1	BCR 215	Health , Hospital and Drug Administration	MCC	3	1	-	4
2	BCR 202	Organizational Behavior	MCC	3	1	-	4
3	BCR 217	Preclinical Studies-I	MCC	3	1	-	4
4	BCR 204	Advance Spoken English	SEC	3	-	-	3
5	BCR 218	Marketing Management	AEC	3	1	-	4
6	BCR 219	MS- Word	SEC	1		1	2
7	PPT 001	Presentation	SEC	-	-	2	1
8	SE 002	Social Engineering/Yoga/Sports/Extra Curricular activity	AEC				NC
9	MO 002	MOOCs/Foreign Language	AEC				NC
10	SSE 002	Soft skill Enhancement –II	SEC	1			NC
Total				17	4	3	22
Cumulative Total				34	9	3	44
SEMESTER III							
1	BCR 310	Pharmacology- III	MCC	3	1	-	4
2	BCR 311	Medical Therapeutics-II	MCC	3	1	-	4
3	BCR 312	Bio ethics & Biosafety-I	AEC	3	1	-	4
4	BCR 304	Global Regulations of Clinical Trial-I	MCC	3	1	-	4

5	BCR 313	Communication Skills	DSE	2	1	-	3
6	BCR 306/307	Elective-1	MLC	2	1	-	3
	BCR E061	MS Excel	SEC	2	-	-	2
7	SSE 003	Soft Skills enhancement –III	SEC	-	-	-	NC
8	SE 003	Social Engineering / Yoga/Sports/Extra Curricular activity	AEC	-	-	-	NC
9	MO 003	MOOCs/Foreign Language	AEC	-	-	-	NC
Total				17	6		24
Cumulative Total				51	15	3	68
SEMESTER IV							
1	BCR 401	Pharmacology-IV	MCC	3	1	-	4
2	BCR 402	Medical Therapeutics-IV	MCC	3	1	-	4
3	BCR 403	Fundamentals of Clinical Trials Operations-I	MCC	3	1	-	4
4	BCR 404	Molecular Diagnostics-I	AEC	3	1	-	4
5	BCR 405/406	Elective-2	MLC	2	1	-	3
6	BCR 407/409	Elective-3	MLC	2	1		3
7	BCR 408	Analytical and Clinical Biochemistry-I	SEC	2	-	-	2
8	SE 004	Social Engineering NSS/YOGA/SPORTS ACITIVITY/Extra Curricular Activity	AEC				NC
9	MO 004	MOOCs/Foreign Language	AEC				NC
10	WN 001	Webinar	AEC				NC
Total				17	6	1	24
Cumulative Total				68	21	4	92
SEMESTER V							
1	BCR 501	Fundamentals of Pharmacovigilance and safety reporting	MCC	3	1	-	4
2	BCR 502	Healthcare Administration	MCC	3	1	-	4
3	BCR 503	Quality in Healthcare and Total Quality Management	SEC	3	1	-	4
4	BCR 504	Ethics in Clinical Research	MCC	3	1	-	4
5	BCR 506/507	Elective-4	MLC	2	1	-	3
6	BCR 508/510	Elective 5	MLC	2	1		3
7	BCR 509	Minor Project Report	CAP	1	1		2
8	SE 005	Social Engineering/ NSS/YOGA/SPORTS ACITIVITY/Extra Curricular Activity	AEC				NC
9	MO 005	MOOCs/Foreign Language	AEC				NC
10	WN 002	Webinar	AEC				NC
Total				17	7	0	24
Cumulative Total				85	28	4	116
SEMESTER VI							

1	BCR 601	INTERNSHIP or Major Project Report	CAP	20			20
Total				20			20
Grand Total				105	28	4	136
L – Lecture 1L = 1Hr	T- Tutorial 1T= 1 Hr	P- Practical 1P=1 Hr	C-Credits 1C = 1 Hr of Theory Paper per week = 2 Hrs of Practical/Tutorial per week				

NC – Non-Credit

S No.	Category	Course Code	Course Title	Semester
1	MAJOR CORE COURSE (MCC)			
2	CORE	BCR 101	Management Concepts	I
3	CORE	BCR 103	Introduction to Healthcare	I
4	CORE	BCR 104	Fundamentals of Clinical Research	I
5	CORE	BCR 201	Health, Hospital and Drug Administration	II
6	CORE	BCR 202	Organizational Behavior	II
7	CORE	BCR 203	Preclinical Studies	II
8	CORE	BCR 301	Pharmacology – I	III
9	CORE	BCR 302	Medical Therapeutics – I	III
10	CORE	BCR 304	Global Regulations of Clinical Trials	III
11	CORE	BCR 401	Pharmacology – II	IV
12	CORE	BCR 402	Medical Therapeutics – II	IV
13	CORE	BCR 403	Fundamentals of Clinical Trial Operations	IV
14	CORE	BCR 501	Fundamentals of Pharmacovigilance & Safety Reporting	V
15	CORE	BCR 502	Healthcare Administration	V
16	CORE	BCR 504	Ethics in Clinical Research	V
	SKILL ENHANCEMENT COURSE (SEC)			
1	SEC	BCR 102	Spoken English	I
2	SEC	BCR 105	Mind Management and Human Values	I
3	SEC	BCR 106	Environmental Science	I
4	SEC	SSE 001	Soft Skill Enhancement – I	I
5	SEC	BCR 204	Advance Spoken English	II
6	SEC	BCR 206	MS Word	II
7	SEC	PPT 001	Presentation	II
8	SEC	SSE 002	Soft Skill Enhancement – II	II
9	SEC	BCR E061	MS Excel	III
10	SEC	SSE 003	Soft Skill Enhancement – III	III
11	SEC	BCR 408	Analytical & Clinical Biochemistry	IV
12	SEC	BCR 503	Quality in Healthcare & Total Quality Management	V
	DISCIPLINE-SPECIFIC ELECTIVE COURSE (DSE)			

1	DSE	BCR 305	Communication Skills	III
MULTI- DISCIPLINARY COURSE (MLC)				
1	MLC	BCR 306/307	Elective – I	III
2	MLC	BCR 405/406	Elective – II	IV
3	MLC	BCR 407/409	Elective – III	IV
4	MLC	BCR 506/507	Elective – IV	V
5	MLC	BCR 508/510	Elective – V	V
ABILITY ENHANCEMENT COURSE (AEC)				
1	AEC	BCR 205	Marketing Management	II
2	AEC	BCR 303	Bioethics & Biosafety	III
3	AEC	BCR 404	Molecular Diagnostics	IV
4	AEC	MO 001	MOOCs / Foreign Language	I
5	AEC	MO 002	MOOCs / Foreign Language	II
6	AEC	MO 003	MOOCs / Foreign Language	III
7	AEC	MO 004	MOOCs / Foreign Language	IV
8	AEC	MO 005	MOOCs / Foreign Language	V
9	AEC	SE 001	Social Engineering / Yoga / Sports / Extra-Curricular	I
10	AEC	SE 002	Social Engineering / Yoga / Sports / Extra-Curricular	II
11	AEC	SE 003	Social Engineering / Yoga / Sports / Extra-Curricular	III
12	AEC	SE 004	Social Engineering / NSS / Yoga / Sports	IV
13	AEC	SE 005	Social Engineering / NSS / Yoga / Sports	V
14	AEC	WN 001	Webinar	IV
15	AEC	WN 002	Webinar	V
CAPSTONE PROJECT (CAP)				
1	CAP	BCR 509	Minor Project Report	V
2	CAP	BCR 601	Internship / Major Project Report	VI

Elective Courses (ELE)

Specialization Electives**

Elective 1.

- BCR 306 Basics of Bioscience
- BCR 307 Human Resource Management
- BCR 314 Software training in Clinical research part 1

Elective2.

- BCR 405 Basics of Epidemiology
- BCR 406 Exposure to Software Training Argus

Elective3

- BCR 407 Research Methodology
- BCR 409 Medical Record Management
- BCR 410 Software training in Clinical research part 2

Elective 4

- BCR 505 Project Management
- BCR 506 Medical Writing
- BCR 507 Clinical Data Management

Elective 5

- BCR 508 Hospital Management and Law
- BCR 509 Minor project report
- BCR 510 Software Training in Clinical Research part 3 and 4

Students will choose one subjects from electives semester wise**

CAPSTONE PROJECT (CAP): List

CAP	Major Project Report
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SEMESTER I

Program	Bachelor of Science Clinical Research	Semester I
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Course Name	Management Concept	L	T	P	C
Course Code	BCR111	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	Explain basic principles and functions of management.
2	Describe major management theories and approaches.
3	Apply decision-making, leadership, and communication skills.
4	Analyze organizational behaviour and teamwork dynamics.
5	Demonstrate effective managerial and problem-solving skills in organizations.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Define management and its role.	L2
CO2	Illustrate evolution of management and Human Resource Movement.	L3
CO3	Classify plans and decisions.	L3
CO4	Analyze the Meaning and types of Centralization and De-centralization.	L3
CO5	Elaborate the importance of directing a leadership.	L4

Syllabus:

Unit-1	Introduction and Nature of Management	Contact Hr
	<ul style="list-style-type: none"> Definition & Meaning of management -By P. F. Drucker, S. George, role of Management in Art, Science and Profession, Distinction between Administration and Management, Importance & major Functions of Management 	10
Unit-2	Evolution of Management	
	<ul style="list-style-type: none"> Thought, Pre Scientific Management era, Scientific Management & Contribution of F. W. Taylor, Process Management & contribution of Henri Fayol, HR movement – Hawthorne experiments, Contributions of Behavioral scientists- Abraham Maslow, Peter Drukker, Douglas Mc. Gregor 	10
Unit-3	Nature & Definition of Planning	
	<ul style="list-style-type: none"> Koontz o’Donnel, Hart, Alfred & Beaty, Importance and limitations, Planning process, Types of Plans- on the basis of use, functions, time (meaning only), Meaning of Decision making, Steps in decision making, Types of decisions- Programmed-Non-programmed; Strategic-tactical, Individual-Group, Policy-Operation, Organizational-Personal 	10
Unit-4	Meaning & Definition	
	<ul style="list-style-type: none"> Koontz O’Donnell & McFarland, Organizing - Nature, Purpose & Principles, Types of Organization (Formal & Informal), Types of Authority relationships- 	8

Line, Functional, Line& staff, Committees, Meaning and types of Departmentation, Centralization and De-centralization (Meaning only)		
Unit-5	Introduction & Importance of Directing, Leadership	
<ul style="list-style-type: none"> • Meaning & Styles, Motivation: importance & Theories (Maslow, Herzberg. Mcgregor), Communication- Meaning, Objectives & Types of communication, Meaning, Principles and techniques of Co-ordination, Meaning, Need & steps in Controlling. 		7

Suggestive Readings:

Text Books:

1. Management: Principles, Processes & Practices Author: R. Srinivasan
2. Organizational Behaviour Author: Stephen P. Robbins & Timothy A. Judge

Reference Books:

1. Fundamentals of Management Author: R. B. Gupta
2. Management: Tasks, Responsibilities, Practices Author: Peter F. Drucker

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	2								2
CO2:	2								2
CO3:		2				2			3
CO4:					2	3			2
CO5:						2			3

Program	Bachelor of Science Clinical Research	Semester I			
Course Name	Spoken English	L	T	P	C
Course Code	BCR112	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	To improve fluency and accuracy in spoken English.
2	To enhance professional communication skills for clinical research settings.
3	To develop confidence in presentations, interviews, and group discussions.
4	To strengthen pronunciation, vocabulary, and clinical terminology usage.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Spell the sentences and pronunciation	L2
CO2	Explain noun, verbs and adjectives in spoken English.	L3
CO3	Analyse the bio-data and CV.	L3
CO4	Discuss various aspects of mock interview session & Design debate and seminar presentations	L4,L5

Syllabus:

Unit-1	Contact Hr
<ul style="list-style-type: none"> Article writing/Paragraph writing Rules of Public Speaking Interview skills Resume Building Vocabulary building /Pronunciation Letter Writing 	10
Unit-2	
<ul style="list-style-type: none"> Why Spoken English – Linguistic Aspects of Mishearing – Fluency - Speaking to Multicultural/Multidisciplinary Audience - Standard Varieties of Spoken English – Tempo of Speech & Phrasal Pause in English – English Rhythm - Stress on Simple and Derived Words in English – Long Vowels in English – Friction Consonants in English – Aspects of Theatre in Spoken Communication – Grooming, Eye Contact, Body Language, Amplitude – Preparing a Presentation : Charts, Graphs, Drawings, Maps, Diagrams, Tables, Etc – Research and Organization – Using Power Point Slides and Other Presentation Aids – Practice and Learning to Improve Pronunciation of Numbers, Units of Weights, Distance, Etc. – Making Presentations and 	13

Self-Evaluation		
Unit-3		
<ul style="list-style-type: none"> Netiquettes Formal dressing Confidence building Difference between a Bio-data/C.V Swot-Analysis Attitude building, Leadership skills Personal hygiene and grooming Non-Verbal and Verbal Communication 		12
Unit-4		
<ul style="list-style-type: none"> Mock Interview session Extempore Group discussion Debate Presentation-students will make a PPT on a common topic and present it in the class. 		10

Suggestive Readings:

Text Books:

1. Advanced Spoken English -Flourish Your Language by Robert Carmen
2. Advanced Spoken English (English Improvement for Success) by Madan Sood

Reference Books:

1. Practical English Usage by Michael Swan
2. English Grammar in Use (Advanced levels) by Raymond Murphy

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	2								2
CO2:	2								2
CO3:		2				2			3
CO4:					2	3			2
CO5:						2			3

SEMESTER I

Program	Bachelor of Science Clinical Research	Semester-I			
Course Name	Introduction to Healthcare -I	L	T	P	C
Course Code	BCR113	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	Describe the basic structure and functions of the healthcare system.
2	Explain the roles of healthcare professionals and organizations.
3	Apply basic healthcare concepts to clinical research settings.
4	Differentiate between various healthcare delivery models and services.
5	Assess the importance of ethics, quality, and patient safety in healthcare.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Find out the Career opportunity in Health Care Systems in India.	L2
CO2	Explain holistic health, Nutrition and First Aid/Cardiopulmonary resuscitation	L3
CO3	Identify foundations of Health and Healthcare System.	L3
CO4	Examine Primary Health Care and Health Services.	L4,L5
CO5	Assess programmes and Policies regarding the health care system.	L3

Syllabus:

Unit-1		Contact Hrs
	<ul style="list-style-type: none"> Introduction of healthcare and major Career opportunity in Health Care, Major Qualities of a Health Care Worker and Health Care Providers , Health Care Systems in India, Measurement , Medical Terms used in healthcare system, Legal Obligations , Cultural Considerations, Medical Liability and Patient's Rights , Ethical and major Roles and Responsibilities of a Health Care Worker. 	10
Unit-2		
	<ul style="list-style-type: none"> Holistic Health, Mental Health, Nutrition, Controlling Infection, Measuring Vital Signs and other Clinical Skills, Injury and Prevention, First Aid/ CPR 	10
Unit-3	Foundations of Health and Healthcare System	
	<ul style="list-style-type: none"> Concept of health & disease: Concept of Prevention, Preventive Medicine, History of Hospitals. Characteristics Hospitals as industry, Community Medicine & Hospitals. 	10
Unit-4	Introduction to Primary Health Care	
	<ul style="list-style-type: none"> Definition, Principles, Functions, Evolution of Health Care System. Organization of Health Services at central, state & district level including Municipal Corporations & Councils, Panchayat Raj institutions. Inter-sectoral linkages. 	8
Unit-5	Hospitals in healthcare industry	

- National health policy, National Rural and Urban Health Mission to protect people. National Health Programmes. International Health Agencies. Concepts of family welfare. MCH and RCH Programmes.

7

Suggested Readings:

Text Books:

- Health Care Reforms in India – Rajendra Pratap Gupta
- Introduction to Health Care – Sharon B. Buchbinder & Nancy H. Shanks.

Reference Books:

- Innovation in Health Care Management- VK Singh & Paul Lillrank
- India's Healthcare Industry – Lawton Robert Burns

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 2 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1 to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	2			1		2			
CO2:	2			2		1			
CO3:	2		2	1		1		1	
CO4:	2		2	2		1		1	
CO5:	2		2	2	2	2	1	1	

SEMESTER I

Program	Bachelor of Science Clinical Research	Semester-I
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Course Name	Fundamental of Clinical Research Core	L	T	P	C
Course Code	BCR114	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	Define key terms and basic concepts of clinical research.
2	Explain the phases and processes of clinical trials.
3	Apply Good Clinical Practice (GCP) principles in research scenarios.
4	Differentiate between study designs and research methodologies.
5	Assess ethical and regulatory requirements in clinical research.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Select the career opportunities in Clinical Research	L2
CO2	Explain and discuss Clinical Trials and its phases.	L2
CO3	Identify the objectives, concept and scope of Intellectual Property Rights for applications in pharmacy	L4
CO4	Simplify the study of Bioavailability and Bioequivalence and their analysis.	L3
CO5	Elaborate the good clinical practice and Schedule Y	L5

Syllabus:

Unit-1	Overview, Opportunities & Career options in Clinical Research	Contact Hrs
	<ul style="list-style-type: none"> Terminologies used in clinical research, GCP guidelines. Historical Aspects of clinical research, Brief description of different phases of clinical trial, Stakeholders role in clinical research, Need for clinical research, Areas used in clinical research. 	10
Unit-2	Introduction of Clinical Trials and its phases	
	<ul style="list-style-type: none"> Types, Randomized/Non randomize Clinical Trial, E-clinical trials- introduction-advancement in drug discovery and development process. Flow chart– cutting costs in clinical trial. 	10
Unit-3	Overview of global and local players	
	<ul style="list-style-type: none"> Advantages of conducting Clinical Research in India. Intellectual Property Rights: Introduction, Scope, Objectives of IPR in pharmacy, Indian legal system & its role in IPR; Concept of property with respect to intellectual creativity; Tangible & Intangible property, concept of IPR, scope & nature of patents, copyrights, trade mark, geographical limitations; Indian Patent Act 1970, Patenting in India & abroad, practical aspects of patent filing, components of a patent application in India. 	10
Unit-4	Bioavailability and Bioequivalence	
	<ul style="list-style-type: none"> Definition, Needs, Methods and Procedures, factors affecting Bioavailability Bioequivalence/ Therapeutic Equivalence, Study parameters: T-max, C-max, AUC, t_{1/2}, Test method to assess Bioequivalence, Steady State studies, regulatory requirements, planning & design, Protocol/ CRF outline, QA & QC, Drug accountability, Elements of BE study, Facilities for conducting BA-BE 	8

Unit-5	National good clinical practice and schedule Y	
Critical evaluation of literature- Systematic review and Meta-analysis,evidence based medicine		7

Suggested Readings:

Text Books:

1. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., DupinSpriet T., Simon P. Publisher: Karger.
2. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. SheinChung Chow, Jen-Pei Liu. Publisher: Wiley.

Reference Books:

1. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier.

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 2 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3					2			2
CO2:	3	2	3	1	2		1	2	
CO3:			1		3				
CO4:	2	3	2					2	
CO5:	1		2		3		3		

SEMESTER I

Program	Bachelor of Science Clinical Research				Semester-I			
Course Name	Mind Management and human value				L	T	P	C

Course Code	BCR115	2	1	0	3

Course Objectives:

This course ensures that the students understand how:

1	Identify basic concepts of mind management and human values
2	Explain the importance of emotional balance and ethical behavior.
3	Apply stress management and positive thinking techniques in daily life.
4	Assess personal values and their role in professional conduct.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Define the framework of human decision making.	L1
CO2	Explain and develop the skill so the student the Area of health.	L2
CO3	Identify and analyze the principles of human structure.	L3
CO4	Compare and adapt the cash management methods	L4,L5

Syllabus:

Unit-1		Contact Hrs
	<ul style="list-style-type: none"> • Concept of Health – Holistic approach to health, Basic information relating to health, Historical development of health care system in India- Determinants to health - Responsibility for Health – Health & Development – Indicators of Health- Concept of Disease – Concept of Causation – Natural History of Disease – Concepts of Control – Modes of Intervention. 	10
Unit-2		
	<ul style="list-style-type: none"> • Understanding values in human-human relationship; meaning of Justice (nine universal values in relationships) and program for its fulfilment to ensure mutual happiness; Trust and Respect as the foundational values of relationship, Understanding the meaning of Trust; Difference between intention and competence 	10
Unit-3		
	<ul style="list-style-type: none"> • Understanding the harmony in the society (society being an extension of family): Resolution, Prosperity, fearlessness (trust) and co-existence as comprehensive Human Goals 6. Visualizing a universal harmonious order in society- Undivided Society, Universal Human Order- from family to world family. 	5
Unit-4		
	<ul style="list-style-type: none"> • Indian Health system Primary, Secondary and Tertiary Care – District Health Organisation - Regionalisation- Inter-sectorial coordination - Indigenous system and medical care – IEC and commUnity participation–Demography and Family Planning – Demographic cycle 	5

Suggested Readings:

Text books:

1. **Human Values and Professional Ethics** – R. R. Gaur, R. Sangal & G. P. Bagaria (Excel Books)

2. Universal Human Values – Dr. C. S. G. Krishnamacharyulu & Dr. Lalitha Ramakrishnan

Reference Books:

1. **A Textbook on Professional Ethics and Human Values – R. S. Naagarazan**2. **Human Values and Ethics: In Search of Organizational Integrity – Debangshu Chakraborty & Shitangshu Kumar Chakraborty****Assessment Scheme**

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 2 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	2			2		2			
CO2:	3	2	2	3	1	2	2	2	
CO3:	3		2	2				2	
CO4:						3			2

Program	Bachelor of Science Clinical Research	Semester-I
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Course Name	Environmental Science-I	L	T	P	C
Course Code	BCR116	2	0	0	2

Course Objectives:

This course ensures that the students understand how:

1	Recall basic concepts of environment, ecosystems, and biodiversity.
2	Explain the impact of human activities on natural resources and ecosystems.
3	Apply environmental protection and sustainability practices in daily life and research.
4	Examine environmental problems and their causes in local and global contexts.
5	Assess strategies for pollution control, conservation, and sustainable development.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Define Multidisciplinary Nature of Environmental Studies and its scope.	L2
CO2	Explain Renewable and Non-Renewable Resources.	L3
CO3	Build up the structure of an ecosystem and identify its types	L3
CO4	Compare different biodiversity in India.	L4,L5
CO5	Determine Environmental Pollutions.	L1

Syllabus:

Unit-1	The Multidisciplinary Nature of Environmental Studies	Contact Hrs
	<ul style="list-style-type: none"> Definition, scope and importance. Need for public awareness. Plastic waste management. 	5
Unit-2	Natural Resource Renewable and Non Renewable Resources	
	<p>Natural resources and associated problems Forest resources: Use and over-exploitation, deforestation. Timber extraction, mining, dams and their effects on forests and tribal people. Water resources: Use and over-utilization of surface and ground water, floods, drought, conflicts over water, dams-benefits and problems. Mineral Resources: Use and exploitation, environmental effects of extracting and using mineral resources.</p> <p>Food resources: World food problems, changes caused by agriculture and overgrazing, effects of modern agriculture, fertilizer-pesticide problems, water logging, salinity. Energy resources: Growing energy needs, renewable and non-renewable energy sources, use of alternate energy sources. Land resources: Land as a resource, land degradation, man induced landslides, soil erosion and desertification. Role of an individual in conservation of natural resources and equitable use of resources for sustainable lifestyle.</p>	10
Unit-3	Ecosystems Concept of an ecosystem	
	<ul style="list-style-type: none"> Structure and function of an ecosystem, - Producers, consumers and decomposers, - Energy flow in the ecosystem, - Ecological succession, - Food chains, food webs and ecological pyramids, - Introduction, types, characteristic features, structure and function of the following ecosystem, - Forest ecosystem, - Grassland ecosystem, - Desert ecosystem, - Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries) 	5

Unit-4	Biodiversity and its conversation Introduction	
	<ul style="list-style-type: none"> Definition: Genetic, species and ecosystem diversity, - Bio - geographical classification of India, - Value of biodiversity: Consumptive use, productive use, social, ethical, aesthetic and option values, - Biodiversity, - India as a mega-diversity nation, - Hot-spots of biodiversity, - Threats to biodiversity: habitat loss, poaching of wildlife, man-wildlife conflicts, - Endangered and endemic species of India, - Conservation of biodiversity: In-situ and Ex-situ conservation of biodiversity. 	5
Unit-5	Environmental Pollution	
	<ul style="list-style-type: none"> Definition, Causes, effects and control measures of: Air pollution, - Water pollution, - Soil pollution, -Marine pollution, - Noise pollution, - Thermal pollution, - Nuclear hazards. Solid waste management: Causes, effects and control measures of urban and industrial wastes, - Role of an individual in prevention of pollution, - Pollution, - Disaster management: Floods, earthquake, cyclone and landslides. 	5

Suggested Readings:

Text books:

1. K. C. Agarwal, (2001) Environmental Biology, 3rd edition, Nidi Publ. Ltd, Bikaner.
2. Bharucha Erach, The Biodiversity of India, 2nd edition, Mapin Publishing Pvt, Ltd, Ahmedabad, India.

Reference Books:

1. R. S. Clark, Marine Pollution, 2nd edition, Clarendon Press Oxford (TB).
2. W.P. Cunningham, Cooper, T. H. Gorhani & M. T. Hepworth, (2001) Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196P.

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 2 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	1								
CO2:	2			1					
CO3:	2			2					
CO4:	2			2					

CO5:	2		1	2	2				
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Semester II

Program	Bachelor of Science Clinical Research	Semester-II			
Course Name	Health Hospital and Drug Administration	L	T	P	C
Course Code	BCR215	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	Recall basic concepts of healthcare systems, hospital management, and drug regulation.
2	Explain roles of hospitals, regulatory authorities, and pharmaceutical governance.
3	Apply administrative and regulatory principles in clinical research settings.
4	Examine policies, processes, and workflows in hospital and drug administration.
5	Assess compliance, quality standards, and ethical practices in healthcare and drug administration.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Define Concept of health & disease.	L2
CO2	Illustrate Concepts of Healthcare industry	L3
CO3	Construct and organize structure of hospital.	L3
CO4	Assess drug management system in Hospital and drug licenses.	L4,L5
CO5	Choose drugs and other consumable materials.	L1

Syllabus:

Unit-1	Concept of health & disease and well-being	Contact Hr
	<ul style="list-style-type: none"> Natural history of disease and role of hospitals to offer various levels of care. Prevention aspect of diseases. Dynamics of disease transmission. 	7
Unit-2	Concepts of Healthcare industry	
	Its ever-changing character Planning – terminal planning, design and operation. Concept of hospitals – planning and design of a hospital (building & physical layout)– space required for separate functions, overview, design & planning of different types of hospitals. Problems and constraints in different type of hospitals, Department and organization structure of different types of hospitals (teaching / non-teaching / general / multi-specialty /super-specialty)	10
Unit-3	Structure and organization of hospital	
	<ul style="list-style-type: none"> Vertical & horizontal; clinical & non-clinical supportive & ancillary service departments in hospitals. Changing pattern of diseases. Common pathological conditions. Pathogenesis of common diseases. Basic concepts of interpretation of investigations reports .Basics of human anatomy and physiology 	10
Unit-4	Drug management system in Hospital and drug licenses	
	<ul style="list-style-type: none"> Narcotics drug storage, Pharmacy billing, Computerized drug management system, Rational use of drugs and prescription audit, Spurious drugs, banned drugs 	10

Unit-5	Purchase of drugs and other consumable materials	
<ul style="list-style-type: none"> Procedure of drug indenting, On time drug dispensing inventory control- ABC, VED, SDE, FSN analysis. Methods of ordering- two bin system (lead time, buffer stock, reorder level) cyclic system 		8

Suggestive Readings:

Text book:

1. Textbook of Hospital Administration – Sonu Dr. Goel
2. Textbook of Medical Administration and Leadership – Erwin Loh & Paul W. Long (Springer)

Reference Books:

1. Handbook of Hospital Administration – Madhav
2. The Truth Pill: The Myth of Drug Regulation in India – Dinesh Thakur & Prashant R. Thikkavarapu

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 2 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	2			3					
CO2:	2	1		2		3			
CO3:	2	1				3			
CO4:	1	2	2		2	2		2	
CO5:	1	2				2		2	

Program	Bachelor of Science Clinical Research	Semester-II			
Course Name	Organizational Behaviour	L	T	P	C
Course Code	BCR202	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	To understand the fundamentals, models, and scope of Organizational Behaviour.
2	To explain individual behaviour factors such as personality, learning, perception, attitudes, and values.
3	To apply motivation and leadership theories to improve workplace performance.
4	To analyze group behaviour, teamwork, decision-making, and conflict management.
5	To evaluate organizational culture, power, change, stress, and contemporary management practices.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Define the organizational behavior in individual, group and organizational level.	L1
CO2	Explain individual behavior	L2
CO3	Identify motivation and leadership	L3
CO4	Analyze the foundations of group behavior	L4
CO5	Evaluate the organizational dimensions.	L5

Syllabus:

Unit-1	Conceptual Foundation of Organizational Behaviour	Contact Hr
	<ul style="list-style-type: none"> Nature and Characteristics, Determinants, Contributing Disciplines, Behaviour – Individual & organizational, and Self Image, Challenges and Opportunities for OB, Models and Approaches of OB.-National 	10
Unit-2	Personality	
	Concept, Theories, Determinants, Personality types, Major personality attributes, Personality-Job fit. Learning: Concept and Theories of Learning, Managerial Implication of Learning Theories. Perception: Process, factors, Attribution theory, perceptual shortcuts and errors, Management and Behavioural Applications of Perception. Attitude: Concept, Process and Importance, Attitude Measurement, Attitude Change, Personal Values and Beliefs.	10
Unit-3	Motivation	
	<ul style="list-style-type: none"> Nature & Process, Early and Contemporary theories of Motivation, Applications of Motivation Concept. Leadership:Nature, Significance and Theories of Leadership, Leadership Effectiveness Model, Leadership traits & Skills, Behavioral Styles in Leadership. Transactional Analysis, Life Position, Johari Window Model 	10

Unit-4	Group Behavior	
	<ul style="list-style-type: none"> Nature, Concept and Stages of Group Formation, Theories of Group Formation. Group vs Team. Group Decision Making: Meaning, nature and process, Techniques of Decision Making. Conflict Management: Definition and types of Conflict, Conflict Process, Individual, Group Level and Organization level Conflict, Conflict Management, Negotiations- Meaning & Process, Issues in Negotiations 	8
Unit-5	Organizational Culture	
	<ul style="list-style-type: none"> Concept, Creating and Sustaining Culture, Employees Learning of the Culture, Creating a Customer-Responsive Culture. Organization Power and Politics: Nature & Concepts, Sources & Types of Power, Techniques of Politics. Organizational Changes: Concept and Forces for Change, Resistance to Change, Approaches to Manage Organizational Change, Organizational Development, Creating a Learning Organization. Stress: Causes & Consequences, Managing Stress, Knowledge Management & Emotional Intelligence in Contemporary Business Organization 	7

Suggestive Readings:

Textbooks:

1. **Organizational Behaviour** – Stephen P. Robbins, Timothy A. Judge & Neharika Vohra

2. **Organizational Behaviour: Text and Cases** – Kavita Singh

Reference Books:

1. **Behavior in Organizations** – Jerald Greenberg & Robert A. Baron (Pearson)

2. **Organizational Behaviour** – Fred Luthans (Tata McGraw Hill)

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:						3			
CO2:	2			2		2			
CO3:						3			
CO4:				2		2			
CO5:					2	2			

Program	Bachelor of Science Clinical Research	Semester-II
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Course Name	Pre-Clinical Studies-I	L	T	P	C
Course Code	BCR217	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	Define basic concepts and objectives of pre-clinical studies.
2	Explain in-vitro and in-vivo study designs and their significance.
3	Apply GLP and ethical guidelines in pre-clinical research settings.
4	Analyze pre-clinical data for safety and toxicity evaluation.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Understand the role of Finding & Development department in Pre-Clinical studies.	L1, L2
CO2	Explain High throughput Screening.	L3
CO3	Identify in-vitro and in-vivo studies and animal models.	L4
CO4	Design the steps in clinical studies & Elaborate drug development process.	L6, L5

Syllabus:

Unit-1	<ul style="list-style-type: none"> Introduction, Factors to be considered for animal studies, Animal models of diseases, Teratogenicity, Mutagenicity, Carcinogenicity. Role of F&D department in Pre-Clinical trial, GLP, Toxicity Studies. Global Level.
Unit-2	Introduction, Advantages and Disadvantages, Uses, Methodology, Cell based Assays.
Unit-3	<ul style="list-style-type: none"> Selection of animal models, Overview of study types, Pre-clinical studies to be performed before phase I, II and III. Differences between in vitro study and in vivo study.
Unit-4	<ul style="list-style-type: none"> Objectives, Importance of Pre-Clinical trials, Steps involved in pre-clinical studies, Drug Development process, Types of Pre-Clinical Studies.

Suggestive Readings:

Text books:

1. Pre-clinical Drug Development, Edited by Mark Rogge, David R. Taft, Second Edition, 25th Sep 2009.

2. Drug Design to Clinical Research – ICRI

Reference Books:

1. A Comprehensive Guide to Toxicology in Pre-clinical Drug Development, Ali S. Faqi, Second

Edition, 2013.

2. Pre-Clinical evaluation of new drugs, S K Gupta.

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3		3		2				
CO2:	2	3							
CO3:	3	2	3	2					
CO4:	3	2	3	2	2	2	2	2	
CO5:	3		3		2	2		2	2

Program	Bachelor of Science Clinical Research	Semester-II
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Course Name	Advance Spoken English	L	T	P	C
Course Code	BCR204	3	0	0	0

Course Objectives:

This course ensures that the students understand how:

1	Explain advanced grammar and pronunciation rules for professional communication.
2	Develop fluency in spoken English for academic and clinical settings.
3	Identify appropriate language and tone for interviews and presentations.
4	Build confidence through structured speaking and feedback practice.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Use correct grammar and clinical terminology in spoken communication.	L1, L2
CO2	Participate effectively in group discussions and professional interactions.	L3
CO3	Demonstrate improved pronunciation, fluency, and confidence.	L3
CO4	Deliver structured presentations and professional talks independently.	L6, L5

Syllabus:

Unit-1	Contact Hrs
<ul style="list-style-type: none"> Use of advanced tenses and modals in speech, Idioms, phrasal verbs, and collocations, Word stress, syllable stress, and intonation basics, Transition words and discourse markers in conversation 	10
Unit-2	
Role plays: At the doctor's, bank, airport, restaurant, etc. Telephone and video call etiquette, Expressing emotions, opinions, preferences, and disagreements politely, Small talk and icebreakers	12
Unit-3	
Techniques for effective group discussions (GD), Managing interruptions, turn-taking, and consensus building, Mock interviews: HR, academic, and technical, Body language and grooming	13
Unit-4	
Speech organization: Introduction, body, and conclusion, Formal presentations using PPT, Persuasive and extempore speaking, Confidence building through stage presence	10

Suggested Readings:

Textbooks:

1. Chaudhary, Shreesh (1992/2004) Better Spoken English, New Delhi: Vikas Publishing.
2. A Practical Course in Spoken English (J.K. Gangal) PHI.

Reference Books:

1. Exploring spoken English Ronald Carter (Cambridge University)

2. Advanced Spoken English , Madan Soo

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	2	1							2
CO2:	2			1	1	2			2
CO3:	1					2			3
CO4:	1								2
CO5:	2	1		1	1	2			3

Program	Bachelor of Science Clinical Research	Semester-II
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Course Name	Marketing Management	L	T	P	C
Course Code	BCR218	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	Understand the basic concepts, nature, scope, and importance of marketing.
2	Learn market segmentation, targeting, positioning, and consumer behaviour concepts.
3	Understand product, branding, packaging, and product life cycle concepts.
4	Learn pricing methods, distribution channels, and marketing communication process.
5	Understand promotion mix, rural and services marketing, and modern marketing challenges.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Explain the fundamentals of marketing, marketing environment, and marketing mix.	L2
CO2	Describe market segmentation, targeting, positioning, and consumer buying behaviour.	L2
CO3	Apply product, branding, packaging, and product life cycle concepts in marketing situations.	L3
CO4	Analyze pricing decisions, distribution channels, and marketing communication strategies.	L4
CO5	Evaluate promotion mix, rural and services marketing, and marketing challenges in the modern era.	L5

Syllabus:

Unit-1	Content	Contact Hrs
	INTRODUCTION TO MARKETING	
	<ul style="list-style-type: none"> Introduction to marketing, Definition Nature, Scope of marketing, Importance of Marketing, types of Marketing Modern marketing concepts in international context, Marketing Management tools and functions of marketing, Concept Marketing vs Selling, 4P's of marketing, Marketing Environment – Micro and MacrEnvironment 	10
Unit-2	SEGMENTATI ON & CONSUMER BEHAVIOUR	
	Segmentation & Consumer Behaviour Market Segmentation, Purpose and Basis of market segmentation, Market Targeting, Product Positioning, Product Positioning Strategy. Consumer	10

Behaviour: Meaning and Its Importance, Consumer decision making process, Determinants of Consumer Behaviour,		
Unit-3	PRICING CONCEPT AND OBJECTIVES	
Product Life Cycle-Product, Classification of product, New Product Development: Process, Product Life cycle, Stages of Product Life cycle, Product Line and Product Mix, Branding, types of Brands, importance of branding, Packaging.		10
Unit-4	COMMUNICATION PROCESS	
Pricing Concept and objectives, Factors Affecting Pricing Decisions, Pricing Methods, Pricing Strategies. Channels of Distribution: Nature and Importance, Types and Levels of Distribution channels, Factors affecting channel distribution, Retailing and Wholesaling Basic Entry		8
Unit-5	PROMOTION COMMUNICATION PROCESS	
Promotion Communication Process, Importance of Promotion, Promotion Mix, Advertising, Sales Promotion, Personal Selling, Publicity, Public Promotion, Personal Selling, Publicity, Public Promotion, Personal Selling, Publicity, Public Relations. Overview of Rural Marketing, and Services Marketing, Marketing Challenges in 21st Century		7

Suggested Readings:

Textbooks:

1. Kotler, P. and Keller, K. L. (2005)
2. Marketing Management. (12 ed.). Prentice Hall

Reference Books:

1. Chandrasekar, K. S. (2010) Marketing management-Text and Cases (1 ed.). Tata McGraw Hill

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1 to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3	2							
CO2:	3	3				1			
CO3:	3	2	2						

CO4:	2	3	2	2	1				
CO5:	2	3	2	2	1	2	1	1	1

Program	Bachelor of Science Clinical Research	Semester-II
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Course Name	MS- Word	L	T	P	C
Course Code	BCR 219	1	0	1	2

Course Objectives:

This course ensures that the students understand how:

1	Understand the basic features and interface of word processing software.
2	Learn to format text, paragraphs, pages, headers, and footers in documents.
3	Develop skills to insert and manage tables, images, symbols, and equations.
4	Learn to use tools like spell check, track changes, styles, and mail merge.
5	Create professional documents with table of contents, security features, and proper printing options.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Understand the basic interface, tools, and functionalities of Microsoft Word.	L2
CO2	Apply formatting techniques to create professional documents.	L3
CO3	Insert and manage tables, images, charts, and other objects.	L3
CO4	Utilize advanced features like templates, mail merge, and document review tools.	L4
CO5	Prepare and publish well-structured reports and documents for academic and professional purposes.	L5

Unit No.	Content	Lecture Hrs/ contact Hrs (30)
UNIT I	Overview of Word Processing, Opening, Saving, Closing Documents, Interface: Ribbon, Tabs, Groups, Toolbar, Creating, Editing, and Navigating Documents, Shortcut Keys and File Types	5
UNIT II	Font styles, size, color, highlighting, bold/italic/underline, Paragraph formatting: alignment, line spacing, indentation, Bullets and Numbering, Page setup: margins, orientation, page size, Headers, Footers, and Page Numbers	3
UNIT III	Creating and formatting tables, Inserting pictures, shapes, icons, SmartArt, and screenshots, Text wrapping and positioning of images, Captions and Table of Figures, Use of Symbols and Equations	2

UNIT IV	Templates and Styles, Spell Check, Grammar Check, Thesaurus, Find and Replace, Track Changes and Comments, Mail Merge: Letters, Labels, Envelopes	3
UNIT V	Creating Cover Page and Table of Contents, Section Breaks and Columns, Hyperlinks, Bookmarks, and Cross-references, Print Preview and Printing Options	2

Suggested Readings:

Textbooks:

1. Microsoft Office Word 2019 Step by Step – Joan Lambert, Microsoft Press
2. Learn Microsoft Word – Ramesh Bangia, Khanna Book Publishing

Reference Books:

1. **Illustrated Course Guide: Microsoft Office 365 & Word 2016** – Jennifer Duffy & Carol M. Cram
2. **Microsoft Word 2010 Plain & Simple** – Katherine Murray

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	1					2			
CO2:						2			
CO3:	1	1				3			
CO4:						2			
CO5:									

Semester III

Program	Bachelor of Science Clinical Research	Semester-III			
Course Name	Pharmacology III	L	T	P	C

Course Code	BCR310	3	1	0	4
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Course Objectives:

This course ensures that the students understand how:

1	Define basic principles of pharmacology and drug classification.
2	Explain pharmacokinetics and pharmacodynamics of drugs.
3	Apply knowledge of drug actions and dosage forms in clinical contexts.
4	Differentiate mechanisms of action and adverse effects of major drug groups.
5	Assess rational use of drugs and safety considerations.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Find out the various drugs acting on blood and respiratory disease.	L2
CO2	Classify the chemotherapeutic agents.	L3
CO3	Identify the antibacterial, antifungal, antiviral drugs.	L3
CO4	Compare various drugs acting on Central nervous system and Peripheral nervous system	L4
CO5	Elaborate the cancer chemotherapy.	L5

Syllabus:

Unit-1		Contact Hrs
	General Pharmacology: Introduction to Pharmacology, Sources of drugs, Dosage forms and routes of administration, mechanism of action, Combined effect of drugs, Factors modifying drug action, tolerance and dependence.	10
Unit-2		
	Pharmacogenetics. Absorption, Distribution, Metabolism and Excretion of drugs, Principles of Basic and Clinical pharmacokinetics, Adverse Drug Reactions and treatment of poisoning, ADME drug interactions.	10
Unit-3		
	Pharmacology of Peripheral Nervous System: Neurohumoral transmission (autonomic and Somatic), Parasympathomimetics, Parasympatholytics, Sympathomimetics, Adrenergic Receptor and neuron blocking agents, Ganglionic, stimulants and blocking agents, Neuromuscular blocking Agents, Local anesthetic Agents	10
Unit-4		
	Pharmacology of Central Nervous System: Neurohumoral transmission in the C.N.S. general Anesthetics, Alcohols and disulfiram, Sedatives, hypnotics, Anti-anxiety agents and Centrally acting muscle relaxa, Psychopharmacological agents (anti-psychotics) antidepressants anti maniacs and hallucinogens, Anti-epileptics drugs, Anti-Parkinsonian Drugs, Analgesics, Antipyretics, Anti-	8

inflammatory and Anti-gout drugs, Narcotic analgesics and antagonists, C.N .S. stimulants, Drug Addiction and Drug Abuse	
Unit-5	
Drugs Acting on the Gastrointestinal Tract: (a) Antacids, Anti Secretory and Anti-ulcer drugs. (b) Laxatives and anti diarrhoeal drugs. (c) Appetite Stimulants and Suppressants (d) Emetics and anti-emetics. (e) Miscellaneous-Carminatives, demulcents, protectives, adsorbents, astringents, digestants, enzymes and mucolytics.	7

Suggested Readings:

Textbooks:

1. Basic And Clinical Pharmacology, Book by Bertram G. Katzung
2. Essentials of Medical Pharmacology, Book by K. D. Tripathi

Reference Books:

1. **Basic and Clinical Pharmacology** – Bertram Katzung, Anthony Trevor
2. **Pharmacology Made Ridiculously Simple** – James Olson

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3		2	2					
CO2:	3		2						
CO3:	3		2						
CO4:	3		2	2					
CO5:	3		2		1				

Program	Bachelor of Science Clinical Research	Semester-III			
Course Name	Medical Therapeutics-II	L	T	P	C
Course Code	BCR311	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	Define basic concepts of medical therapeutics and treatment principles.
2	Explain therapeutic approaches for common diseases.
3	Apply drug therapy principles in clinical case scenarios.
4	Differentiate treatment regimens based on disease conditions.
5	Assess the safety and effectiveness of therapeutic interventions.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Describe therapeutic management of common medical disorders.	L2
CO2	Interpret treatment plans and drug regimens in clinical settings.	L3
CO3	Compare various therapeutic options for specific diseases.	L4
CO4	Evaluate drug interactions, adverse effects, and patient safety.	L5
CO5	Develop basic therapeutic plans for simulated clinical cases.	L6

Syllabus:

Unit-1		Contact Hrs
	Introduction to clinical medicine – Science and art of medicine, global issues in medicine, screening and prevention of diseases	10
Unit-2		
	Basic climatic and environmental diseases, Diabetes mellitus - Functional anatomy, physiology, presenting problems in Diabetes mellitus, management, drugs-class effect and side effects, dietary management, long term complications in brief	10
Unit-3		
	Hypertension - Definition, types of hypertension, causative factors, pathophysiology, JNC classification of Hypertension, dietary management, treatment (different classes), class effect and side effects	10
Unit-4		
	Coronary artery diseases - Ischemic heart disease ; definition, types, causative factors, pathophysiology, life style modifications, treatment (different classes) ,class effect and side effects in brief	8
Unit-5		
	Cerebrovascular diseases- Stroke; etiology, management; life style modifications, treatment (different classes), class effect and side effects in brief	7

Suggested Readings:

Text books:

1. Harrison's Principles of Internal Medicine, 18th Edition. Dan Longo, Anthony Fauci, Dennis Kasper, Stephen Hauser, J. Jameson, Joseph Loscalzo. Publisher: McGraw-Hill.
2. Davidson's Principles and Practice of Medicine, 22nd Edition. Brian R. Walker, Nicki R Colledge, Stuart H. Ralston, Ian Penman. Publisher: Churchill Livingstone, Elsevier.

Reference Books:

1. Oxford Handbook of Clinical Medicine, 9th Edition. Murray Longmore, Ian Wilkinson, Andrew Baldwin, and Elizabeth Wallin. Oxford Medical Handbooks.

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3			2					
CO2:	3		1						
CO3:	3	1	1						
CO4:	3		2						
CO5:	2		1						

Program	Bachelor of Science Clinical Research				Semester-III			
Course Name	Bioethics and Biosafety-I				L	T	P	C
Course Code	BCR312				3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	Define key principles of bioethics and biosafety.
2	Explain ethical guidelines and regulatory frameworks in clinical research.
3	Apply biosafety practices and ethical standards in research settings.
4	Examine ethical issues and biosafety risks in clinical studies.
5	Assess compliance with ethical and biosafety regulations.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Describe ethical principles governing clinical research.	L2
CO2	Implement biosafety measures in laboratory and clinical environments.	L3
CO3	Analyze ethical dilemmas and risk factors in research scenarios.	L4
CO4	Evaluate adherence to ICH-GCP and national regulatory guidelines.	L5
CO5	Develop ethical and biosafety compliance plans for research projects.	L6

Syllabus:

Unit-1	Regulatory framework in India governing GMOs	Contact Hrs
	Recombinant DNA Advisory Committee (RDAC), Institutional Biosafety Committee (IBC), Review Committee on Genetic Manipulation, Genetic Engineering Approval Committee (GEAC), State Biosafety Coordination Committee (SBCC), District Level Committee (DLC). Recombinant DNA Guidelines (1990), Revised Guidelines for Research in Transgenic Plants (1998), Seed Policy (2002), Prevention Food Adulteration Act (1955), The Food Safety and Standards Bill (2005), Plant Quarantine Order (2003), Regulation for Import of GM Products Under Foreign Trade Policy (2006-2007), National Environment Policy (2006). Rules for the manufacture, use/import/export and storage of hazardous microorganisms/genetically engineered organisms or cells_(Ministry of Environment and Forests Notification,1989	15
Unit-2	Convention of Biological Diversity (1992)	
	Cartagena Protocol on Biosafety – Objectives and salient features of Cartagena Protocol – Advanced Information Agreement (AIA) procedure – procedures for GMOs intended for direct use-risk assessment-risk management-handling, transport, packaging and identification of GMOs- Biosafety Clearing House-unintentional transboundary movement of GMOs-Benefits of becoming a party to the Cartagena Protocol- status of implementation in India	10
Unit-3	Legal implications	
	Biodiversity and farmer rights. Intellectual property rights-TRIPS, GATT-International conventions patents and methods of application of patents	10
Unit-4	Fundamentals of bioethics	
	The legal and socioeconomic impacts of biotechnology - Public education of the process of biotechnology involved in generating new forms of life for informed decision-making – ethical concerns of biotechnology research and innovation	10

Suggested Readings:

Textbooks:

1. Beier, F.K., Crespi, R.S. and Straus, T. Biotechnology and Patent protection-Oxford and IBH Publishing Co. New Delhi

2. **Bioethics and Biosafety in Biotechnology** – V. Sree Krishna

Reference Books:

1. **Bioethics and Biosafety** – M. K. Sateesh

2. **Biosafety and Bioethics** – Rajmohan Joshi

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	2		2		3	2	3	2	
CO2:	2		1		3		2		
CO3:					3		3	2	1
CO4:					3	1	3	2	2
CO5:	1	2	2		2	2	2		

Program	Bachelor of Science Clinical Research			Semester-III			
Course Name	Global Regulations of Clinical Trials-I			L	T	P	C
Course Code	BCR304			3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	Define key regulatory bodies and guidelines governing clinical trials.
2	Explain global regulatory frameworks such as ICH-GCP and national regulations.

3	Apply regulatory requirements in clinical trial documentation and conduct.
4	Compare regulatory processes across different countries.
5	Assess compliance and ethical standards in global clinical trials.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Describe roles of global regulatory authorities in clinical research.	L2
CO2	Implement regulatory guidelines in trial planning and reporting.	L3
CO3	Differentiate approval processes and submission requirements internationally.	L4
CO4	Evaluate compliance with global ethical and safety standards.	L5
CO5	Develop regulatory submission plans for multinational clinical trials.	L6

Syllabus:

Unit-1	Contact Hrs
Background of drug regulations, International Conference on Harmonization, history of ICH, ICH Structure, ICH Guidelines, Good Clinical Practice- Elements and principle of GCP.	10
Unit-2	
Application: requirements forms , contents, application , Investigator IND, Treatment IND , Emergency use of IND. NDA application: contents , forms , review process, actions, Guidance documents for IND and NDA, Common Technical Document: Purpose , structure and contents.- National level.	10
Unit-3	
Regulatory Requirements in China , regulatory system in China , SFDA Structure and Functions, SFDA technical organizations , regulations in China , Regulatory requirements in Japan and Australia, regulatory authorities and laws related to CR, Regulations in other counties related to Clinical Research.	10
Unit-4	
Food and Drug Act (USFDA), Organization structure and Functions, Code of Federal Regulations related to Clinical Research, EU regulations: EU Clinical Trial Directives, EMEA Structure and Functions, MHRA, Eudralex	8
Unit-5	
Global Regulations for Medical Devices, Classification of medical Devices, Regulatory agencies and regulations, Clinical Trials of Medical Devices; Regulations for Biological products; Types of Biological products. Drug Development for Orphan diseases and Drug legislation	7

Suggested Readings:

Text Books:

1. US Guidance for Clinical Research, ICRI
2. Applied Regulations, ICRI

Reference Books:

1. MRC Guidelines for Good Clinical Practice in Clinical Trials, ICRI
2. Guidance for Investigational New Drug Applications, ICRI

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3		2		3		3	2	
CO2:	2	2	3		2			2	
CO3:	2		3		2		2	2	
CO4:	3	2	3		2			2	
CO5:	2	2	3		3	1	2	2	1

Program	Bachelor of Science Clinical Research	Semester-III			
Course Name	Communication Skills	L	T	P	C
Course Code	BCR313	2	1	0	3

Course Objectives:

This course ensures that the students understand how:

1	Identify basic principles and types of communication.
2	Explain verbal, non-verbal, and written communication processes.
3	Apply effective communication techniques in academic and clinical settings.

4	Examine barriers to communication and strategies to overcome them.
5	Assess the role of professional and ethical communication in healthcare.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Describe effective communication methods in clinical research.	L2
CO2	Demonstrate clear and professional verbal and written communication.	L3
CO3	Analyze communication scenarios and respond appropriately.	L4
CO4	Evaluate personal communication skills and improve through feedback.	L5
CO5	Prepare professional reports, presentations, and research communications.	L6

Syllabus:

Unit-1	Contact Hrs
Defining Communication, Nature of Communication, Process of Communication, Objectives of Communication, Forms and Dimensions of Communication, Oral and Written Communication	10
Unit-2	
Job Applications and Resume Writing, Business letters, Enquiries, Orders & replies, Circulars, Notices and Memos	5
Unit-3	
Business reports, Academic report writing, Business etiquette, Enriching Vocabulary, Paragraph development	5
Unit-4	
Extempore and Prepared Speeches, Planning and Delivering Presentations, Using Audio-Visual Aids, Overcoming Stage Fright, Body Language and Voice Modulation	5
Unit-5	
Group Discussions: Preparation and Participation, Mock Interviews and Feedback, Meetings: Agendas and Minutes, Business Communication: Reports and Proposals, Email Etiquette and Netiquette	5

Suggested Readings:

Textbooks:

1. Speaking and Writing for Effective Communication, Author Francis Soundararaj, Publisher Macmillan.
2. M.K. Sehgal and Vandana Khetarpal, Publisher- Excelbooks.

Reference Book:

1. Effective Business Communication-Author HertaA. Murphy,HerbertW. Hilde Publisher-Tata Mc. Grawhil

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	2			1					
CO2:	2	2			1				2
CO3:							2		3
CO4:							2		3
CO5:									

Semester IV

Program	Bachelor of Science Clinical Research	Semester-IV			
Course Name	Pharmacology-IV	L	T	P	C
Course Code	BCR401	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	To outline the classification of drugs acting on major organ systems.
2	To explain mechanisms of action and therapeutic uses of systemic drugs.

3	To apply pharmacological principles in disease management.
4	To differentiate drug classes based on efficacy and safety profiles.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	List major drugs used in cardiovascular, endocrine, CNS, and infectious diseases.	L1
CO2	Describe mechanisms, indications, and adverse effects of drugs.	L2
CO3	Apply pharmacological knowledge to clinical case scenarios.	L3
CO4	Compare drug therapies based on mechanism and safety.	L4

Syllabus:

Unit-1	Contact Hrs
Hematinic, Anticoagulants, Vitamin K and hemostatic agents, Fibrinolytic and anti-platelet drugs, Blood and plasma volume expanders. Drugs acting on Respiratory system- Anti-asthmatic drugs including bronchodilators, Anti-tussives and expectorants, Respiratory stimulants.	13
Unit-2	Contact Hrs
Alzheimer's drugs mania drugs. Schizophrenia drugs, depression.drugs acting on CNS and peripheral nervous system. Parkinsons disease. Dermatology classification. Outline of renal function, Nephron, Diuretics, Ant diuretics, Drugs which alter the pH of kidney.	12
Unit-3	Contact Hrs
Introduction and definitions with examples, Antibiotics and antibacterial agents , Antifungal agents, Antiviral/antiretroviral agents, Antiprotozoal agents, Antimalarial drugs, Antiseptics and disinfectant. Gastrointestinal drugs.	10
Unit-4	Contact Hrs
Introduction, Chemotherapy of tuberculosis and leprosy, Chemotherapy of Malaria, Chemotherapy of protozoal infections, Pharmacology of Anthelmintic drugs, Cancer Chemotherapy.	10

Suggested Readings:

Textbooks:

- Essentials of Medical Pharmacology. K.D Tripathi, Publisher: Jaypee brothers, 2013, 3rd Edition. Basic and clinical pharmacology, Lange. By [Bertram G. Katzung](#) 11th Edition.
- Goodman and Gilman's the pharmacological basics of therapeutics. 9th Edition.

Reference Books:

- Rang & Dale's Pharmacology** by H.P. Rang, M.M. Dale, J.M. Ritter & R.J. Flower
- Katzung & Trevor's *Basic and Clinical Pharmacology*

Assessment Scheme

Component	Adopted for this	Duration	Weightage	Date &	Venue	Remarks	Levels
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	Course			Time			
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3	2	2	2				1	
CO2:	3	2	2					1	
CO3:	3	2	2				1	1	
CO4:	3	2	3					1	

Program	Bachelor of Science Clinical Research	Semester-IV			
Course Name	Medical Therapeutics- IV	L	T	P	C
Course Code	BCR402	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	To identify therapeutic approaches for major systemic diseases.
2	To explain treatment guidelines and drug regimens for chronic and acute disorders.
3	To apply therapeutic principles in clinical case management.
4	To compare different treatment strategies based on patient conditions.

5	To assess safety, efficacy, and outcomes of therapeutic interventions in clinical research.
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Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	List standard treatment protocols for major diseases.	L1
CO2	Describe mechanisms and rationale of therapeutic regimens.	L2
CO3	Apply treatment guidelines to clinical scenarios.	L3
CO4	Differentiate therapeutic options based on risk–benefit profiles.	L4
CO5	Evaluate therapeutic outcomes and adverse drug reactions in clinical trials.	L5

Syllabus:

Unit-1	Contact Hrs
Arthritis- Rheumatoid arthritis, osteoarthritis- Definition, pathophysiology, treatment - different classes of drugs, class effect and class side effect, pharmacological- classification of drugs, class effect & class side effect & non-pharmacological treatment.	10
Unit-2	
Shock- Definition, pathophysiology, types of shock, presenting features, diagnostic investigation in brief, pharmacological- classification of drugs, class effect & class side effect and non-pharmacological treatment	10
Unit-3	
Inflammatory Bowel Disease and Irritable Bowel Syndrome- Definition, pathophysiology, presenting features, management, investigation, pharmacological classification of drugs, class effect & class side effect & non-pharmacological treatment.	10
Unit-4	
Heart failure, Coronary artery diseases: drugs, surgical treatment in brief & stents	7
Unit-5	
Common infections a) Tuberculosis – causative agents, diagnostic criteria, etiological agents in brief, categories of tuberculosis, classification of drugs, first line drugs in detail different classes of drugs, class effect and class side effect , DOTS therapy, multidrug resistant tuberculosis b) AIDS - Etiological agents in brief, causative agents, diagnostic criteria, treatment, different classes of drugs, class effect and class side effect treatment regimes, prophylactic therapy, therapy in pregnancy c) Malaria- Life cycle of causative agent, types of malaria, causative agents, diagnostic criteria, treatment, different classes of drugs, class effect and class side effect treatment of relapsing malaria, treatment of cerebral malaria, multi drug resistant malaria.	8

Suggested Readings:

Textbook:

1. Harrison's Principles of Internal Medicine, 18th Edition. Dan Longo, Anthony Fauci, Dennis Kasper, Stephen Hauser, J. Jameson, Joseph Loscalzo. Publisher: McGraw-Hill
2. Davidson's Principles and Practice of Medicine, 22nd Edition. Brian R. Walker, Nicki R Colledge, Stuart H. Ralston, Ian Penman. Publisher: Churchill Livingstone, Elsevier.

Reference Books:

1. Oxford Handbook of Clinical Medicine, 9th Edition.

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3	1		3					
CO2:	3	2	2					2	
CO3:	3	1	3					1	
CO4:	3		2		2	2			1
CO5:									

Program	Bachelor of Science Clinical Research				Semester-IV			
Course Name	Fundamentals of Clinical Trial Operation-I				L	T	P	C
Course Code	BCR403				3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	To outline phases and basic components of clinical trials.
2	To explain Good Clinical Practice (GCP) and regulatory requirements.
3	To apply standard procedures in clinical trial conduct and documentation.

4	To examine ethical and operational issues in trial management.
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Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	List phases, stakeholders, and essential documents in clinical trials.	L1
CO2	Describe regulatory guidelines and ethical principles governing trials.	L2
CO3	Perform basic clinical trial operations including documentation and monitoring support.	L3
CO4	Analyze protocol deviations, adverse events, and compliance issues.	L4

Syllabus:

Unit-1	Contact Hrs
Site Selection parameters, Location, Staffing, Qualifications Investigational pharmacy, ICH-GCP compliance, Patient enrollment, Site Selection Check list, Site Initiation Visit (SIV) o Single Centre/Multi Centre Trial- Definition, benefits of Single centre and or Multi centre, Differences between Single centre & Multi centre Trial o Investigator Selection Investigator qualification and agreement, duties delegation, Undertaking by the Investigator, Feasibility study.	13
Unit-2	
Defining Scope of IRB/IEC Authority, Responsibilities of IRB/IEC, Composition of IRB/IEC, Basic Functions, Operation and Procedure of IRB/IEC.	10
Unit-3	
Roles & Responsibilities of Clinical Trial Personnel, Sponsor , Investigator , CROs/SMOs , CRA/Monitor, Auditor o Roles & Responsibilities of Clinical Research Coordinator, Clinical Data Manager.	10
Unit-4	
Clinical Trial Documentation, Investigator's Brochure, Study Protocol, Case Report Forms (CRF) & e-CRF, o Informed Consent Form/Assent Form, Clinical Study Report, Standard Operating Procedures (SOP) in Clinical Trials, Essential Document.	12

Suggested Readings:

Textbooks:

1. Good clinical practice: Consolidated guideline, ICRI
2. White book for Clinical Research, ICRI

Reference Books:

1. CRA handbook, ICRI
2. Basic Principles of Clinical research, S.K.Gupta, ICRI

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3		2	3					
CO2:	2		3		2		3	2	
CO3:	3		3		3	2	3	2	
CO4:		3	3		3		3	3	2

Program	Bachelor of Science Clinical Research			Semester-IV			
Course Name	Molecular Diagnostics-I			L	T	P	C
Course Code	BCR404			3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	To identify basic molecular diagnostic techniques and biomarkers.
2	To explain principles of PCR, sequencing, and hybridization methods.
3	To apply molecular techniques in disease diagnosis and research.
4	To interpret molecular diagnostic results in clinical contexts.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	List common molecular diagnostic tools and their applications.	L1
CO2	Describe the working principles of PCR, ELISA, and sequencing methods.	L2
CO3	Demonstrate basic laboratory workflow in molecular diagnostics.	L3
CO4	Analyze and interpret laboratory results for clinical decision-making.	L4

Syllabus:

Unit-1	Introduction and History of diagnostics	Contact Hrs
	Diseases- infectious, physiological and metabolic errors, genetic basis of diseases, inherited diseases. Infection – mode of transmission in infections, factors predisposing to microbial pathogenicity, types of infectious diseases- bacterial, viral, fungal, protozoans and other parasites.	10
Unit-2	Traditional disease diagnosis methods and tools-NATIONAL	
	Diagnosis of infection caused by Streptococcus, Coliforms, Bacterial, Viral, Protozoan. Diagnosis of DNA and RNA viruses- Pox viruses, Adenoviruses, Rhabdo Viruses, Hepatitis Viruses and Retroviruses. Diagnosis of Protozoan diseases: Amoebiasis, Malaria, Trypanosomiasis.	12
Unit-3	Major Metabolic disorders and its causes-Globally	
	Traditional methods for the diagnosis of metabolic errors. Disease due to genetic disorders - Identifying human disease genes. Cancer- different types of cancers, genetics of cancer- oncogenes, tumor suppressor genes. Methods available for the diagnosis of genetic diseases and metabolic disorders.	13
Unit-4	Molecular Diagnosis: Nucleic acid amplification methods and types of PCR-Global	
	Proteins and Amino acids Hybridization techniques and DNA sequencing methods in molecular diagnosis: Southern, Northern, in-situ (including FISH), Protein extraction and analysis (including PAGE and its variations).	10

Suggested Readings:

Textbooks:

1. Medical Microbiology, Edited by Greenwood, D, Slack, R and Peutherer, J, ELST Publishers.
2. Parasitology, Chatterjee K.D, Chatterjee Medical Publishers.

Reference Books:

1. Bailey & Scott's Diagnostic Microbiology, Betty A. Forbes , Daniel F. Sahn, Alice S. Weissfeld , Ernest A. Trevino, Published by C.V. Mosby
2. Jawetz, Melnick, & Adelberg's Medical Microbiology, Geo F. Brooks, Stephen A. Morse, Janet S. Butel.

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3		2	3					
CO2:	2	2	2						
CO3:				3					
CO4:	2	3	3					2	

Program	Bachelor of Science Clinical Research				Semester-IV			
Course Name	Analytical and Clinical Biochemistry-I				L	T	P	C
Course Code	BCR408				2	0	0	0

Course Objectives:

This course ensures that the students understand how:

1	To identify basic biochemical analytes and analytical techniques used in clinical laboratories.
2	To explain principles of clinical biochemistry tests and instrumentation.
3	To apply analytical methods for estimation of biochemical parameters.
4	To interpret biochemical test results in relation to disease conditions.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	List common biochemical tests and laboratory instruments.	L1

CO2	Describe the principles and procedures of clinical biochemical analysis.	L2
CO3	Perform basic analytical techniques and calculations accurately.	L3
CO4	Analyze and correlate biochemical findings with clinical conditions.	L4

Syllabus:

Unit-1		Contact hrs
	Methods of protein extraction, Protein quantitation: Biuret, Lowry, BCA and Bradford methods, Protein precipitation: Salting-in, Salting-out, Effect of organic solvents and polymers. Protein separation: Dialysis, Ultrafiltration, Centrifugation. Electrophoresis: Definition, principle, factors affecting mobility, paper & gel electrophoresis. Gel Electrophoresis - PAGE, SDS - PAGE, 2D-PAGE, Isoelectric focusing, Capillary electrophoresis. Visualizing separated components National	10
Unit-2		
	Chromatography: Partition coefficient, Retention, Resolution. Gel filtration chromatography, Ion exchange chromatography, Affinity chromatography, Paper chromatography, Thin layer chromatography, Reversed-phase chromatography, High performance chromatography, GLC – Principle and applications. Spectroscopy: Fundamentals of UV Spectroscopy, Spectrophotometer, Fundamentals of fluorescence spectroscopy, Spectrofluorometer.	10
Unit-3		
	Basic concepts of Clinical Biochemistry -Health and disease, Normal and pathological changes, affecting cells in the body - cell death and the physiological causes - physical, chemical and biological agents. Evaluation of biochemical changes in diseases - Basic hepatic, renal and cardiovascular physiology. Biochemical symptoms associated with disease and their evaluation. Diagnostic biochemical profile. Blood - Collection, processing and preservation, Composition - cells, plasma proteins and their variations in diseases. Disorders of Haemoglobin- Thalassemia, Sickle cell anaemia- Microcytic, Normocytic and macrocytic, Normal constitution of blood and their variation under pathological conditions- Urea, Uric Acids, Creatinine, Glucose, Billirubin, Total Protein, Albumin/ Globulin ration. Lipid profile - Cholesterol, Triglycerides, Lipoproteins-HDL, LDL. Interpretation of data for all constituents.	5
Unit-4		
	Urine - Collection, processing and preservation, Characteristics - volume, pH, colour and specific gravity, Chemical analysis and normal value of the constituents - urea, uric acid, creatinine, pigments and their clinical significant. Abnormal constituents- Glucose, Albumin, Ketone bodies and bile pigments and their pathological significant. Liver Diseases -Liver function test and significance. Disorder of live-cirrhosis, hepatitis, fatty liver, jaundice (types) and gall stones. Diagnostic enzymology - Enzymes in diagnosis of various disorders such as liver, cardiac - ALP, SGOT, SGPT, CK, LDH	5

Suggested Readings:

Textbooks:

1. Fundamentals of Enzymology - Nicholas. C. Price and Lewis Stevens, Oxford Science Publications, 3rd Edition, 2009.

2. Enzymes – Biochemistry, Biotechnology, Clinical Chemistry, Trevor Palmer, Philip Bonner, Woodhead Publishing, 2nd Edition, 2007.

Reference Books:

1. Principles and Techniques in Biochemistry and Molecular Biology – Keith Wilson and John Walker, Cambridge University Press, 7th Edition, 2010.

2. Practical Clinical Biochemistry: Methods and Interpretations by Ranjna Chawla, Jaypee Brothers Medical Publishers, 4th Edition, 2014.

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3		2	3					
CO2:	2	2	2						
CO3:				3					
CO4:	2	3	3					2	

SEMESTER V

Program	Bachelor of Science Clinical Research	Semester-V			
Course Name	Fundamentals of Pharmacovigilance and Safety Reporting	L	T	P	C
Course Code	BCR501	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	To define key terms and concepts in pharmacovigilance and drug safety.
2	To explain adverse drug reactions (ADRs) and safety reporting systems.
3	To apply standard procedures for case processing and reporting.
4	To examine causality assessment and signal detection methods.
5	To assess risk–benefit profiles and regulatory safety requirements.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	List types of ADRs and pharmacovigilance terminology.	L1
CO2	Describe safety reporting workflows and regulatory guidelines.	L2
CO3	Perform basic Individual Case Safety Report (ICSR) documentation.	L3
CO4	Analyze safety data for causality and signal identification.	L4
CO5	Evaluate drug safety information for regulatory compliance and patient safety.	L5

Syllabus:

Unit-1		Contact Hrs
	Definitions, Overview and Scope, Importance, History: Pre Thalidomide era, Thalidomide Disaster and Post Thalidomide Era; Pharmacovigilance; Drugs withdrawn from the Market; WHO Drug monitoring Programme and Uppsala Monitoring centre. Pharmacovigilance Regulations in India and national PV policy and programme.	10
Unit-2		
	Definitions and classification of ADRs Detection and reporting, Causality assessment, Severity and seriousness assessment.	8
Unit-3		
	Passive Surveillance, Active Surveillance and Stimulated Reporting. PMS Methodologies - Observational studies, Case studies, Cohort studies.	7
Unit-4		
	Actual v/s perceived Risk and benefits, Factors affecting benefit risk balance; Methods of Risk Minimization, Pharmacovigilance Planning, Pharmacovigilance Planning Guidelines.	
Unit-5		
	Drug Safety Guidelines: ICH,WHO etc.PV in Europe, US, India, China, Australia, Japan. Regulations and guidelines of these countries .US FDA med watch, UK Yellow card System. Adverse Event Case Processing, Case Processing Principles, Sources of Individual Case Safety Reports, format and content and compilation of PSURS worldwide.	8
Unit-6		
	Life cycle of a case –Data entry to evaluation, report generation, triage, case review and narrative writing. Case studies. Data entry terminology MEDRA, WHO ART , WHO DD.	7
Unit-7		
	Signal generation, Sources and methods of Signal Detection, Automated quantitative Signal Detection.UMCsignaling Process. PV data base soft wares(Aris, Argus etc. for case report Management.	5

Suggested Readings:

Textbooks:

1. Essentials of Pharmacovigilance, ICRI
2. Recommended text: An Introduction to Pharmacovigilance by Patrick Waller (2010)

Reference Books:

1. Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics by Linda Fossatti Wood and MaryAnn Foote

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3		2	3					
CO2:	2	2	2						
CO3:				3					
CO4:	2	3	3					2	
CO5:									

Program	Bachelor of Science Clinical Research			Semester-V			
Course Name	Healthcare Administration			L	T	P	C
Course Code	BCR502			3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	To outline basic principles and functions of healthcare administration.
2	To explain healthcare systems, policies, and organizational structures.
3	To apply management principles in healthcare and clinical research settings.
4	To examine quality assurance, budgeting, and resource management practices.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level

CO1	List components of healthcare systems and administrative functions.	L1
CO2	Describe healthcare policies, accreditation standards, and management processes.	L2
CO3	Apply administrative and leadership skills in healthcare organizations.	L3
CO4	Analyze operational challenges and propose solutions for effective healthcare delivery.	L4

Syllabus:

Unit-1		Contact Hrs
	Nutrition and Dietary services – Pharmacy services – Medical Records services.	13
Unit-2		
	Facilities Engineering – Maintenance of Civil Assets – Electrical supply and Water supply – Medical gas pipeline – Plumbing and Sanitation – Air conditioning system – Hot water and Steam supply – Communication Systems –Biomedical engineering departments in modern hospitals.	12
Unit-3		
	Laundry services – House keeping services – CSSD-Energy conservation methods – AMC. UNIT IV Ambulance services – Mortuary services – Hospital security services.	8
Unit-4		
	Disaster management – Fire hazards – Engineering Hazards – Radiological hazards.-Outsourcing of Support services –Waste disposal and management - few case studies.	7

Suggested Readings;

Textbooks:

1. G.D.Kunders, HOSPITAL AND FACILITIES PLANNING AND DESIGN
2. Jacob Kline, HAND BOOK OF BIO-MEDICAL ENGINEERING

Reference Books:

1. Webster J.G and Albert M. Coe, CLINICAL ENGINEERING PRINCIPLES AND PRACTICES
2. Antony Kelly, MAINTENANCE PLANNING AND CONTROL

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9

(CO)									
CO1:	2	2	1			2			
CO2:	2		3	1	3		2	3	
CO3		2		2			1		
CO4			2			1		2	

Program	Bachelor of Science Clinical Research	Semester-V			
Course Name	Quality in Healthcare and Clinical Quality Management	L	T	P	C
Course Code	BCR503	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	To define basic concepts of quality assurance and quality control in healthcare.
2	To explain quality management systems and accreditation standards.
3	To apply quality tools in clinical and research settings.
4	To examine root causes of errors and deviations in healthcare processes
5	To assess quality improvement strategies and compliance requirements

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT
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		Level
CO1	List principles, indicators, and standards of healthcare quality.	L1
CO2	Describe quality assurance programs and regulatory guidelines.	L2
CO3	Implement basic quality control and audit procedures.	L3
CO4	Analyze process deviations using quality improvement tools.	L4
CO5	Evaluate quality management systems for continuous improvement and patient safety.	L5

Syllabus:

Unit-1		Contact Hrs
Quality / Customer Service; Define Customer and Identify Customers, Customer Experience: Core Service & Delivery of Service Excellent Customer Service ,Caring Service Individual Behaviour =: Stress, Communication and Interpersonal Relationship Patient Satisfaction Rights and Responsibilities of Patients Satisfaction and Delight Quality Indicators of Patient Satisfaction Clinical Quality Complication and Infection Rate Admission.		13
Unit-2		
Follow Up and Continuity of Care Measuring Quality Setting Objectives and Agreeing upon Standards Develop Key Result Areas and Performance Indicators Feedback: Customers, Staff, Suppliers, etc. Quality Audit and Review Techniques.		10
Unit-3		
Definition of TQM, malcon Bridge national quality award defined, comparison of quality on the basis of different parameters, Developing quality specification, cost of quality functions of the Quality Cost department.		12
Unit-4		
Six sigma methodology, analytical tools for six sigma and continuous improvement, six sigma roles and responsibilities.		10

Suggested Readings:

Textbooks:

1. Raandi Schmidt J. Trumbo and R. Jonson, Quality in Health Care Sector – ASQC Quality Press.
2. Quality Improvement in Health Care, 2nd Ed, Nelson Thrones

Reference Books:

1. *Quality Demystified: A Comprehensive Guide to Quality Improvement, Patient Safety, and Clinical Audit in Healthcare* – Sangeeta Sharma (Springer Singapore, 2025)
2. *Quality in Healthcare: A Lean Six Sigma Project Approach* – Corinne M. Karuppan, Nancy E. Dunlap & Robert Cavagnol (Springer Publishing, 2025)

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	☑	1.5hr	15			Traditional	Levels 1 to 5
Assignment	☑		5			Group	Levels 1 to 5

Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	2			3					
CO2:		2	2					2	
CO3:		3	3		2	2			
CO4:			2		2	3		2	1
CO5				2			3		

Program	Bachelor of Science Clinical Research			Semester-V			
Course Name	Ethics in Clinical Research			L	T	P	C
Course Code	BCR504			3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	To define basic ethical principles and guidelines in clinical research.
2	To explain informed consent, confidentiality, and participant rights.
3	To apply ethical principles in clinical trial conduct.
4	To examine ethical issues and protocol deviations in research studies.
5	To assess compliance with ethical and regulatory standards.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT
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		Level
CO1	List major ethical guidelines and regulatory bodies governing clinical research.	L1
CO2	Describe principles such as autonomy, beneficence, non-maleficence, and justice.	L2
CO3	Demonstrate proper informed consent and documentation procedures.	L3
CO4	Analyze ethical dilemmas in clinical research scenarios.	L4
CO5	Evaluate research studies for ethical compliance and participant safety.	L5

Syllabus:

Unit-1		Contact Hrs
	A historical overview; Codes related to ethics: highlights of Nuremberg code, Declarations: contents of Declaration of Helsinki and its importance Ethical Guidelines: the Belmont Report, C.I.O.M.S (W.H.O) guidelines.	10
Unit-2		
	Ethical Issues in RCT. Use of Placebo, Vulnerable Subjects; Ethics in Stem Cell Research, Transplantation, Assisted Reproductive Technologies; Biotech products and Medical devices.	10
Unit-3		
	Composition, Power and Review procedure; Ethics Committee: Role and responsibilities in a clinical trial, Conflict of interest in Clinical research: types of conflicts of interest and its avoidance.	10
Unit-4		
	Historical overview, protection of subjects, Informed consent process, Patient Information Sheet, Informed Consent form, HIPAA. ICMR and Indian GCP Guidelines.	8
Unit-5		
	Types of insurance, contractual agreements, Human volunteers & Compensation, Privacy and confidentiality in clinical research, Consumer Protection Act.	7

Suggested readings:

1. Ethical guidelines for Biomedical Research on Human Subject, ICRI
2. FDA : Protection of Human Subject, ICRI

Reference Books:

1. Clinical Trials: ensuring Patient Safety and Integrity, ICRI

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3		2				3	3	
CO2:	3		3		3		3	3	
CO3:	2		3		3		3	2	
CO4:		2	3		3		3	3	
CO5:	2		2		3		3	3	

Program	Bachelor of Science Clinical Research	Semester-V			
Course Name	Minor Project Report	L	T	P	C
Course Code	BCR509	1	1	0	2

SEMESTER VI

Program	Bachelor of Science Clinical Research	Semester-VI			
Course Name	Internship or Major Project Report	L	T	P	C
Course Code	BCR 601	0	0	20	20

Elective Courses (ELE)

Specialization Electives**

Elective 1.

BCR 306 Basics of Bioscience

BCR 307 Human Resource Management-II

Elective2.

BCR 405 Basics of Epidemiology

BCR 406 Exposure to Software Training Argus

Elective3

BCR 407 Research Methodology

BCR 409 Medical Record Management

Elective 4

BCR 505 Medical Writing

BCR 506 Clinical Data Management

Elective 5

BCR 508 Hospital Management and Law

BCR 510 Software Training in Clinical Research part 3 and 4

Students will choose one subjects from electives semester wise**

ELECTIVES

ELECTIVE 1

Program	Bachelor of Science Clinical Research	Semester			
Course Name	Basics of Bio-science	L	T	P	C
Course Code	BCR306	2	1	0	3

Course Objectives:

This course ensures that the students understand how:

1	To identify fundamental concepts of cell biology, genetics, and human physiology.
2	To explain structure and functions of cells, tissues, and organ systems.
3	To apply basic biological principles to health and disease conditions.
4	To examine biological processes underlying pathological changes.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
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CO1	List key components of cells, tissues, and major organ systems.	L1
CO2	Describe basic genetic mechanisms and physiological processes.	L2
CO3	Apply bioscience knowledge to interpret disease mechanisms.	L3
CO4	Analyze biological data related to health and disease.	L4

Syllabus:

Unit-1		Contact Hrs
	Random experiments, sample space, events, related results. Classical, empirical, and axiomatic approaches to probability. Properties of probability. Illustrations and applications. Addition theorem. Conditional probability, independence of events. Law of total probability. Bayes theorem and applications	10
Unit-2		
	Arithmetic mean, median, mode, geometric mean, harmonic mean and their properties. Absolute and relative measures of dispersion: range, standard deviation, mean deviation, quartile deviation, coefficient of variation and their properties.	10
Unit-3		
	Major Role of Statistics in Clinical Medicine, Testing of Hypothesis, Role of Statistics in Preventive Medicine, and Observations in Medicines.	5
Unit-4		
	Plan for Data Analysis: Quantitative and Qualitative, Preparing Data for Computer Analysis and Presentation, Statistical Analysis, Interpretation of Data Conclusion and Generalizations, Summary and Discussion.	5

Suggested Readings:

Textbooks:

1. Cochran, W.G. (2002). Sampling Techniques.
2. Wiley Des Raj and Chandhok (1998).

Reference books:

1. Sampling Theory, Narosa. Murthy, M.N. (1967).
2. Sampling Theory and Methods. Statistical Publishing Company, Calcutta. Sampath S.(2005). Sampling Theory and Methods.

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Exam							
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Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3	2	1					2	
CO2:	2	3	2					2	
CO3:	3	2	2	2				2	
CO4:	3	3	3		2			3	2
CO5:	2	2	2		2		1	2	3

ELECTIVE- I

Program	Bachelor of Science Clinical Research	Semester			
Course Name	Human Resource Management	L	T	P	C
Course Code	BCR307	2	1	0	3

Course Objectives:

This course ensures that the students understand how:

1	To define basic concepts and functions of human resource management.
2	To explain recruitment, training, and performance appraisal processes.
3	To apply HR policies in healthcare and clinical research organizations.
4	To examine employee relations and organizational behavior issues.
5	To assess HR strategies for improving organizational effectiveness.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
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CO1	List major HR functions and roles in organizations.	L1
CO2	Describe recruitment, selection, training, and compensation systems.	L2
CO3	Apply HR management principles in clinical research settings.	L3
CO4	Analyze workplace conflicts and employee performance issues.	L4
CO5	Evaluate HR practices to enhance productivity and compliance.	L5

Syllabus:

Unit-1		Contact Hrs
	Nature, Scope, and Importance of HRM, Functions of HRM, Evolution and Development of HRM, Strategic HRM and its role in organizational success, Difference between Personnel Management and HRM	10
Unit-2		
	HR Planning: Objectives and Process, Job Analysis – Job Description and Job Specification, Recruitment: Sources and Methods, Selection Process: Tests and Interviews, Placement and Induction	5
Unit-3		
	Training: Need, Methods (On-the-job and Off-the-job), Evaluation of Training Programs, Management Development, Career Planning and Succession Planning	5
Unit-4		
	Performance Appraisal: Methods and Challenges, Job Evaluation Techniques, Compensation Structure and Factors, Incentives and Benefits, Employee Retention and Motivation	5
Unit-5	10	
	Employee Welfare and Safety, Labour Laws: Overview of key Acts (Factories Act, Industrial Disputes Act, etc.), HRM in the Era of Technology: HRIS and HR Analytics, Diversity Management and Ethical Issues in HR, Global HRM and Emerging Trends	5

Suggested Readings:

Textbooks:

1. K. Aswathappa, Human Resource Management, McGraw Hill
2. Gary Dessler, Human Resource Management, Pearson

Reference books:

1. Michael Armstrong, A Handbook of Human Resource Management Practice, Kogan Page
2. V.S.P. Rao, Human Resource Management, Excel Books

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5

Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	2					3			
CO2:		2	2						
CO3:			3		2				
CO4:						2			
CO5:					3		3	3	

ELECTIVE- II

Program	Bachelor of Science Clinical Research	Semester			
Course Name	Basics of Epidemiology	L	T	P	C
Course Code	BCR405	2	1	0	3

Course Objectives:

This course ensures that the students understand how:

1	Remember basic epidemiological terms and concepts.
2	Understand the principles of disease distribution and determinants.
3	Explain common epidemiological study designs.
4	Apply basic measures of disease frequency in population data.
5	Recognize the role of epidemiology in clinical research and public health.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Define key epidemiological concepts and terminology.	L1
CO2	Describe patterns of disease by person, place, and time.	L2

CO3	Calculate and interpret basic measures such as incidence and prevalence.	L3
CO4	Compare major epidemiological study designs.	L4
CO5	Evaluate the relevance of epidemiological findings in clinical research settings.	L5

Syllabus:

Unit-1	Definition and meaning of Health	Copntact Hrs
	Concept of Health – Holistic approach to health, Basic information relating to health, Historical development of health care system in India- Determinants to health - Responsibility for Health – Health & Development – Indicators of Health- Concept of Disease – Concept of Causation – Natural History of Disease – Concepts of Control – Modes of Intervention.	10
Unit-2		
	Principles of epidemiological studies and epidemiological methods – Types of epidemiological studies, interpreting epidemiological data, surveillance, monitoring, Notifiable diseases, International classification of Diseases (ICD), Death certification - Investigation of an epidemic and role of hospital in its control – Applied epidemiology to hospitals.	5
Unit-3		
	Health for all by 2000 AD and Primary Health Care - Role of Health education and communication – Overview of health policy (NHP-1983-2015, HFA2000, MDG, Five Year plans), National population policy and five year plans – Health committees and their recommendations – National Health Budget –	5
Unit-4		
	Health Care Delivery System Indian Health system Primary, Secondary and Tertiary Care – District Health Organisation - Regionalisation- Inter-sectorial coordination - Indigenous system and medical care – IEC and commUnity participation–Demography and Family Planning – Demographic cycle — Health systems in developed and developing countries, Community involvement & participation, community Health Programmes, Community diagnosis–Maternal & Child Health, Family welfare – Occupational Health- Environmental Health – Genetics – Geriatric Health – Nutrition and health – Mental Health. Social welfare schemes in government & nongovernmental health organizations.	5
Unit-5	Health Education & Communication	
	Principles: Methods, Materials – Communication for health education: Mass Media, Mass Communication – Levels of health information- Health care reporting & Role of NIC Health Planning and management. International Health - International Health agencies/NGOs – International Health Regulations, Emergency epidemic management system.	5

Suggested Readings:

Textbooks:

1. Aquaculture principles and practices ----TVR Pillay and MN Kutty
2. Encyclopedia of aquaculture ----RR Stickney,

Reference books:

1. Hand book fisheries and aquaculture----ICAR New Delhi 2006,

2. Sustainable aquaculture ---- BB Jena and Carl D.Webster

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3	2	2	3				3	
CO2:	2	3	3				1	3	
CO3:			2	3			2		
CO4:	2		3	3	3	2	2		
CO5:					2	2	3		2

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3	2	2	3				3	
CO2:	2	3	3				1	3	
CO3:			2	3			2		
CO4:	2		3	3	3	2	2		
CO5:					2	2	3		2

ELECTIVE- III

Program	Bachelor of Science Clinical Research	Semester			
Course Name	Research Methodology	L	T	P	C
Course Code	BCR407	2	1	0	3

Course Objectives:

This course ensures that the students understand how:

1	Recall fundamental concepts and terminology of research methodology
2	Explain different types of research designs used in clinical research.
3	Apply appropriate methods for literature review and research problem identification.
4	Analyze basic sampling techniques and data collection methods.
5	Understand ethical principles and regulatory considerations in research.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Define key concepts related to research methodology.	L1

CO2	Describe and differentiate various research designs and approaches	L2
CO3	Apply appropriate sampling and data collection techniques in research studies.	L3
CO4	Analyze research data using basic methodological principles.	L4
CO5	Evaluate ethical issues and compliance requirements in clinical research.	L5

Syllabus:

Unit-1	Introduction to Research	Contact Hrs
	Methodology and Method, Types of research- Descriptive vs. Analytical, Applied vs. Fundamental, Quantitative vs. Qualitative, Conceptual vs. Empirical, Concept of Interdisciplinary Research, Procedures in research, Identification of the problem-Literature survey, Experimental methods, Quasi-experimental studies- Survey, Types of surveys- CATI, CAPI, Mail, Email, Face-to-face, Questionnaire	10
Unit-2	Sampling and Analysis	
	Discourse analysis, Biographical Data Analysis, Primary and secondary data, Collection and validation, Methods of sampling- Simple random sampling, Stratified random sampling and Systematic sampling, Attitude Measurement-land Scales, Scaling of attitude , Deterministic attitudes, Measurement models, Summative models.	5
Unit-3	Experimental Design and Hypothesis	
	Factorial experimental design, Designing experiments, Basic principles-replication, randomization, blocking. Single Factor Experiment: Hypothesis design, Hypothesis testing using z- test, t-test, ANOVA etc., Analysis of Variance Components (ANOVA) for fixed effect model	5
Unit-4	Computer Application	
	Introduction to spread sheet application, Features and functions, Using formulas and functions, Data storing, Features for Statistical data analysis, Generating charts/ graph and other features, Power point presentation, Use of software for statistical analysis such as SPSS	5
Unit-5	Research Report	
	Type of research report- contents, Steps in drafting, Editing and evaluating the final draft, Styles for figures, tables, text, quoting of reference and bibliography, Use and format of appendices- Indexing, Structure and presentation of research report, Research ethics, plagiarism.	5

Suggested Readings:

Textbooks:

1. Research Methodology, CR Kothari
2. Responsible Conduct of Research, Adil E. Shamo

Reference books:

1. *Principles of Research Methodology: A Guide for Clinical Investigators* — Edited by Phyllis G. Supino & Jeffrey S. Borer
2. Sustainable aquaculture ---- BB Jena and Carl D. Webster
2. *Clinical Research Methodology and Evidence-Based Medicine* — Ajit N. Babu (2nd edition)

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3	2	2	2				3	
CO2:	2	3	2					3	
CO3:	2		3					3	
CO4:		3						3	
CO5:					3				3

ELECTIVE- III

Program	Bachelor of Science Clinical Research	Semester			
Course Name	Medical Record Management	L	T	P	C
Course Code	BCR409	2	1	0	3

Course Objectives:

This course ensures that the students understand how:

1	Recall fundamental concepts and terminology of medical record management.
2	Explain the structure, content, and types of medical records.
3	Apply principles of documentation, coding, and record maintenance.
4	Understand legal, ethical, and confidentiality requirements in medical record management.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Define key terms and components of medical records.	L1
CO2	Describe different types and formats of medical records, including electronic health records.	L2
CO3	Apply appropriate methods for accurate documentation, storage, and	L3

	retrieval of medical records.	
CO4	Evaluate medical record practices for compliance with legal, ethical, and confidentiality standards.	L5

Syllabus:

Unit- 1		Contact Hrs
	Introduction: Definition with its Types of medical record, Importance of medical record in healthcare management. , Flow chart of its function.	10
Unit-2		
	Statutory requirements of maintenance, coding, indexing and filing, Computerization of record, Report and returns by the record department, Statistical information and ICD. Medical record keeping, Reports & returns in Medical Record System.	10
Unit-3		
	Utility & functions of Medical Records in Health care delivery System, Organizations & management of Medical Records Department, Role of Hospital managers & MRD personnel.	5
Unit-4		
	Basic knowledge of legal aspects of Medical Records including Factories Act, Workmen Compensation Act & Consumer Protection Act, Procedures of Medical Auditing & its importance. Government Regulations & requirement- National.	5

Suggested Readings:

Textbooks:

1. A framework for managing patients medical records
2. Handling the medical claim- Catherine Cochran

Reference books:

1. Functions of a Tertiary Care Hospital – Md. Kamal Hussain

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9

CO1:	3		2	1				1	
CO2:	2	2	3		2		1	1	
CO3:			3		3		2		
CO4:	1	1	2		2			2	1

ELECTIVE- IV

Program	Bachelor of Science Clinical Research	Semester			
Course Name	Medical Writing	L	T	P	C
Course Code	BCR505	2	1	0	3

Course Objectives:

This course ensures that the students understand how:

1	Recall fundamental concepts and terminology related to medical research.
2	Explain various types of medical and clinical research.
3	Apply basic research methods and study designs in medical research.
4	Analyze the role of data collection and interpretation in medical research.
5	Understand ethical principles and regulatory guidelines governing medical research.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Define key concepts and terms used in medical research.	L1
CO2	Describe different types and approaches of medical research.	L2

CO3	Apply appropriate research methods to basic medical research problems.	L3
CO4	Analyze research findings using fundamental scientific principles.	L4
CO5	Evaluate medical research studies for ethical conduct and scientific validity.	L5

Syllabus:

Unit- 1		Contact Hrs
	Article Writing: Introduction, Good Publication Practices, Documentation Standards	5
Unit-2		
	Overview of scientific articles, Reviews, Research articles, systematic review, meta analysis, commentary, letter to editor, editorials, etc.	5
Unit-3		
	Literature search and pub med search, Article writing : Exercises and examples, Article submission, selecting target journal, Letter writing for editorial process, Reviewing, editing and publishing	5
Unit-4		
	Referencing software, article writing software, and plagiarism software	5
Unit-5		
	Duties of Author, Authorship dispute, Editor, Reviewer, etc. Guidelines of ICMJE and other bodies, Guidelines and Checklists of relevant to medical writing in diverse medical fraternities, Publication Ethics, Journal quality and impact assessment of article, Common technical document (CTD) dossier writing.	5
Unit-6		
	Clinical study report, Grant proposal, Leave behind literature. Pharmacovigilance writing: ICSR, SAE reporting, Narratives, PSUR, DSUR, etc.	5

Suggested Readings:

Textbooks:

1. Asher R. How to present your article. BMJ, 2: 502, 1958.
2. Stephen Lock Thornes's better medical writing, Pitmen Medical, 2nd Ed. 6. 1977.

Reference books:

1. Fraser HS. Writing a scientific paper. West Indian Med J; 44 (4): 114-24, 1995.
2. Bradford Hill A. Logical order for a scientific paper. BMJ; 2: 870, 1965.

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	2								3
CO2:	2		2						3
CO3:		3						2	
CO4:		3			2		2		
CO5:	2		3		3	2	2	2	3

ELECTIVE- IV

Program	Bachelor of Science Clinical Research	Semester			
Course Name	Clinical Data Management	L	T	P	C
Course Code	BCR506	2	1	0	3

Course Objectives:

This course ensures that the students understand how:

1	Recall fundamental concepts and terminology of clinical data management.
2	Explain the clinical data lifecycle and data flow in clinical trials.
3	Apply basic principles of data collection, validation, and quality control.
4	Analyze common data management issues in clinical research.
5	Understand regulatory and ethical requirements related to clinical data management.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Define key terms and processes in clinical data management.	L1
CO2	Describe the stages of the clinical data lifecycle in research studies.	L2

CO3	Apply appropriate methods for data entry, cleaning, and validation.	L3
CO4	Analyze clinical datasets to identify errors and inconsistencies.	L4
CO5	Evaluate clinical data management practices for compliance with regulatory and quality standards.	L5

Syllabus:

Unit-1	Contact Hrs
Introduction to CDM, Computer system validation (CSV), Clinical Data Management flow, Data Management team, Roles and responsibilities of key team members and sponsor, SOPs of data Management, review and authorization. CRF design, Procedure for CRF designs, elements of CRF, data points to be captured in individual CRFs. Database design and build. Introduction to data base design and build, data base design, data base validation. Clinical data entry process, Data entry screen validation, data entry process, symbols, data entering. Guidelines and regulations in Clinical Trial data	10
Unit-2	
Terminology and definitions, quality control process, data errors and quality measurement, responsibilities, operational QC, data management matrix, QA in Clinical data management.	5
Unit-3	
Introduction, Types of dictionaries, types of Coding. Types of queries, Management of queries, SAE reconciliation.	5
Unit-4	
Introduction to data base lock, minimum standards, procedure, errors found after database closure, freezing the data base, best practices, recommended Standard Operating Procedures. Introduction to data transfer, procedure, best practices.	5
Unit-5	
Electronic data interchange-Architecture for EDI, Advantages of using EDI, barriers to implementation, positives and negatives, Lab data loading -Roles and responsibilities of lab loader technician, helpdesk, study coordinator, -loading lab data, electronic/lab file contents, typical problems, lab data findings, Quality Assurance, SOPs for processing lab data, taking lab data seriously.	5

Suggested Readings:

Textbooks:

1. **Practical Guide to Clinical Data Management** by *Susanne Prokscha* – A.
2. **The Fundamentals of Clinical Data Management**

Reference books:

1. **Management of Data in Clinical Trials** by *Eleanor McFadden*
2. **Clinical Data Management – A Beginner’s Guide** by *Kamal Akhtar*

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5

Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3	2	3					2	
CO2:		3							
CO3:		3	3		3				
CO4:			3		2				
CO5:		2	3						

ELECTIVE- V

Program	Bachelor of Science Clinical Research			Semester			
Course Name	Hospital Management and Law			L	T	P	C
Course Code	BCR508			2	1	0	3

Course Objectives:

This course ensures that the students understand how:

1	Recall basic concepts and terminology of hospital management and healthcare law.
2	Explain the organizational structure and functions of hospitals.
3	Understand key legal frameworks governing healthcare institutions.
4	Apply basic management principles in hospital and healthcare settings.
5	Recognize ethical and legal responsibilities of healthcare professionals.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Define key terms related to hospital management and healthcare law.	L1
CO2	Describe hospital organization, administration, and management	L2

	functions.	
CO3	Apply management principles to routine hospital operations.	L3
CO4	Analyze legal and ethical issues encountered in hospital and healthcare practice.	L4
CO5	Evaluate compliance of hospital practices with applicable healthcare laws and regulations.	L5

Syllabus:

Unit- 1		Contact Hrs
	Forming Society, The Companies Act, and Law of Partnership A Sample Constitution for the Hospital, relevant State Act, Factories Act, Shops and Establishment Act, The Workmen's Compensation Act, The Employee's State Insurance Act, The Employees Provident Funds Act, The Payment of Gratuity Act.	10
Unit-2		
	The Maternity Benefit Act, The Payment of Wages Act; The Minimum Wages Act, The Industrial Disputes Act, The Industrial Employment (Standing Orders) Act, The Trade Union Act, The Apprentices Act The Employment Exchanges (Compulsory Notification of Vacancies) Act, The Collection of Statistics Act Medical Council of India; Medical Licensure Law, Doctors Patient Relationship.	5
Unit-3		
	Medical Malpractice, Quality and Standard of Medical Care, Negligence, Medical Consent Emergency Care, The Consumer Protection Act, Patients Rights and Responsibilities, Medical Ethics, Mental Illness, Tuberculosis, Drugs Addicts and Alcoholics, Legal Issue in Death Cases, Legal Testimony in Medico-legal cases.	5
Unit-4		
	Narcotic Laws, The Drugs and Cosmetic Act, Drug Control Policy, Clinical Investigation, Blood Transfusion, The Medical Termination of Pregnancy Act, The Prenatal Diagnostic.	5
Unit-5		
	Meaning of property, Is IP a property, Justifications for protection of IP, Major forms of IP i. Copyright ii. Patent iii. Trade Marks iv. Designs v. Geographic indication vi. Semi conductor's vii. Plant varieties 5. Major international documents relating to the protection of IP i. Berne Convention ii. Paris Convention iii. TRIPS.	5

Suggested Readings:

Textbooks:

1. Kapoor, N.D; 2004: Mercantile Law – Sultan Chand & Sons: New Delhi(Chapter 1-5)
2. Kuchhel, M.C. 2003, Marcentile Law; Vikas Publishing Private Ltd. New Delhi (chapter 1-5)

Reference books:

1. Pathak, Legal Aspect of Business, TMH
2. P.L Mallick – Industrial Law – Eastern Book Company – Lucknow

Assessment Scheme

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid Term	<input checked="" type="checkbox"/>	1.5hr	15			Traditional	Levels 1 to 5
Assignment	<input checked="" type="checkbox"/>		5			Group	Levels 1 to 5
Class Test	<input checked="" type="checkbox"/>	30mins	10			MCQ	Level 1to 3
Comprehensive Exam	<input checked="" type="checkbox"/>	3hr	70			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1:	3		2						
CO2:	2		2		2				
CO3:	2		3	1	2				
CO4:	2		3		3		2		
CO5:	1		2		3				2